BACKGROUND:

The Genetic Information Non-Discrimination Act (GINA), also known as H.R. 493, aims to protect individuals’ rights to non-discrimination (in insurance and employment) on the basis of personal genetic information.

With the mapping of the human genome in 2003, and the subsequent identification of genes and markers for a multitude of diseases and conditions, concern has grown over the issue of insurance company or employer access to individual genetic information, with strong opinions being voiced on either side of the issue. Interested parties have argued that GINA needs to be implemented as it stands, while others say that the bill needs overhauled before it should be passed because it is too vague. Public opinion also varies on this topic.

ACTIVITY:

Your assignment is to address the House of Representatives and advise either:

- in support the bill, as-is,  
- to advocate what revisions, amendments or additions should be made before passing.

You will be placed on a team representing one of four interested groups. You should argue your group’s position as strongly as possible, regardless of your personal opinions (these may be exercised after the activity). There are assigned readings for each group. You are responsible only for the readings designated to your party. Other groups’ readings are optional, but may help you formulate responses to possible objections.

As a team, you will present your advice to the class. Your instructor will tell you how many minutes you have to present. You should factor in time to receive a few questions and give responses.

WITNESS GROUPS:

Group 1: American Civil Liberties Union (ACLU)
Group 2: Genetic Information Nondiscrimination in Employment Coalition (GINE)
Group 3: Insurance Companies against GINA
Group 4: Employers’ coalition for the Right to Screen.

A brief position statement from each of the groups will follow.
ACTIVITY SCHEDULE:

Step one:
Independently read the background material and the article(s) representing the viewpoint to which you have been assigned. As you read, you may wish to highlight, underline or take notes on information that you think is particularly relevant or convincing in support of your position. Make sure you understand your arguments and that you can defend your position in your own words.

Step two:
Assembling with your group, discuss the key points you have identified. Take turns sharing your information. You may find you have selected the same points as other members of your team, or you may have different points highlighted. Discuss how you will present your case.

Step three:
Each group will have the opportunity to present their arguments. Listen to the other groups’ opinions and take notes. You will have the opportunity to pose questions and raise objections after each presentation. REMEMBER, each group has been assigned a point of view. You must stay focused on the issue and refrain from personal attacks.

Step four:
Class discussion. You can now discuss the issues arising freely from your own personal viewpoint.

Step five:
Each student is required to write a one page reflective summary of this activity. In this summary you are required to explain what GINA is and the main arguments in favor and against this act. Please present some of your own personal presentations in this reflective summary.
POSITION SUMMARIES:

Group 1: American Civil Liberties Union (ACLU)
The ACLU considers itself our nation's guardian of liberty, working daily in courts, legislatures and communities to defend and preserve the individual rights and liberties that the Constitution and laws of the United States guarantee everyone in this country. This case focuses on the following rights: freedom of speech, association and assembly; freedom of the press, and freedom of religion; right to equal protection under the law - protection against unlawful discrimination; right to due process - fair treatment by the government whenever the loss of your liberty or property is at stake; right to privacy - freedom from unwarranted government intrusion into your personal and private affairs. The ACLU also works to extend rights to segments of our population that have traditionally been denied their rights, including people of color; women; lesbians, gay men, bisexuals and transgender people; prisoners; and people with disabilities. If the rights of society's most vulnerable members are denied, everyone's rights are imperiled.

Group 2: Genetic Information Nondiscrimination in Employment Coalition (GINE)
The GINE Coalition is a group of employers, national trade associations, and professional organizations formed to address concerns about workplace discrimination based on employees' genetic information, as well as the confidentiality of that information. The Coalition strongly supports genetic nondiscrimination and confidentiality, and believes that employment decisions should be based on an individual’s qualifications and ability to perform a job, not on genetic characteristics which may have no bearing on job performance.

Group 3: Insurance Companies against GINA
The business of insurance requires that underwriters accurately assess the risks that they are insuring against. These insurance companies believe that they should be allowed access to all the information available to accurately predict the risks associated with providing insurance for an individual. This will allow insurance companies to charge the proper premiums in order to cover the payoffs that must be made to the people they insure. These insurance companies believe that genetic privacy laws will allow high-risk insurees, who are entitled to withhold knowledge of their genetic predisposition to certain conditions, to lie about their health in order to obtain/continue to receive coverage. This will undoubtedly result in healthier customers being charged more to pay for their high-risk counterparts.

Group 4: Employers’ coalition for the right to screen
This is a coalition of concerned employers, many of whom represent the chemical industry. The goal is to support the right of employers to conduct pre-employment screening, and ongoing genetic testing, of employees to ensure the continued health and safety of our workforce. It recognizes that certain individuals, as a result of their genetic makeup, may be more susceptible to certain workplace hazards, for example the effects of chemicals and radiation. The right to screen will allow employers the ability to avoid placing workers in environments which may cause them harm.
BACKGROUND READING FOR ALL GROUPS:

What's genetic discrimination?

Genetic discrimination occurs if people are treated unfairly because of differences in their DNA that increase their chances of getting a certain disease. For example, a health insurer might refuse to give coverage to a woman who has a DNA difference that raises her odds of getting breast cancer. Employers also could use DNA information to decide whether to hire or fire workers.

Who needs protection from genetic discrimination?

Everyone should care about the potential for genetic discrimination. Every person has dozens of DNA differences that could increase or decrease his or her chance of getting a disease such as diabetes, heart disease, cancer or Alzheimer's disease. It's important to remember that these DNA differences don't always mean someone will develop a disease, just that the risk to get the disease may be greater.

More and more tests are being developed to find DNA differences that affect our health. Called genetic tests, these tests will become a routine part of health care in the future. Health care providers will use information about each person's DNA to develop more individualized ways of detecting, treating and preventing disease. But unless this DNA information is protected, it could be used to discriminate against people.

What's the Genetic Information Nondiscrimination Act (GINA)?

The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, is a new federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health. The new law prevents discrimination from health insurers and employers. The President signed the act into federal law on May 21, 2008. The parts of the law relating to health insurers will take effect by May 2009, and those relating to employers will take effect by November 2009.

Why is GINA necessary?

The law was needed to help ease concerns about discrimination that might keep some people from getting genetic tests that could benefit their health. The law also enables people to take part in research studies without fear that their DNA information might be used against them in health insurance or the workplace.
What's included in GINA?

The law protects people from discrimination by health insurers and employers on the basis of DNA information.

What's not included in GINA?

The law does not cover life insurance, disability insurance and long-term care insurance.

How does the federal law affect state laws?

Before the federal law was passed, many states had passed laws against genetic discrimination. The degree of protection from these laws varies widely among the different states. The federal law sets a minimum standard of protection that must be met in all states. It does not weaken the protections provided by any state law.

Where can I find more information?

For the text of the bill see: H.R. 493
[http://thomas.loc.gov/cgi-bin/bdquery/z?d110:HR00493]
Mr. Chairman and Members of the Committee:

My name is Ronald Weich. I am a partner in the Washington D.C. law firm of Zuckerman Spaeder LLP and I serve as a legislative consultant to the American Civil Liberties Union (ACLU). I am pleased to submit for the record of this hearing the views of the ACLU on the subject of genetic privacy and nondiscrimination.

The ACLU is a nationwide, non-partisan organization of nearly 300,000 members dedicated to protecting the principles of liberty, freedom and equality set forth in the Bill of Rights to the United States Constitution. For almost 80 years, the ACLU has sought to strengthen civil rights and civil liberties in all aspects of American life.

We commend the Committee for its attention to the important issue of genetic privacy. Recent scientific advances in understanding and mapping the human genome present opportunities for improved medical care, but also pose challenges to principles of privacy and nondiscrimination.

Genetic tests reveal the most intimate and personal health-related information that exists about any individual. While all medical information should be treated as private, genetic information is uniquely sensitive because it may reveal so much about an individual, including the individual's genetic predisposition to medical conditions. Individuals should be allowed to control such quintessentially personal information, and should be empowered by law to shield such information from third parties.

In addition to establishing the privacy of genetic information, federal law should prohibit discrimination in employment or insurance based on genetic information. There are three reasons why Congress should take immediate steps to prohibit the use of such information by employers or insurers:
First, it is inherently unfair to discriminate against someone based on immutable characteristics that do not affect their ability to perform a job.

Second, the mere fact that someone has a genetic predisposition to a health condition is an unreliable basis to act on the risk that he or she will actually develop that condition in the future. Genetic tests do not show with certainty that any individual will eventually develop a disease or how severe their symptoms might be.

Third, the threat of genetic discrimination leads individuals to decline genetic screenings and other health services to avoid revealing information that may be used against them. For example, the Journal of the American Medical Association reports that only 57% of women at risk for breast cancer seek genetic testing, and 84% of those who decline the test do so because they fear genetic discrimination.

Dr. Frances Collins and other leading genetic scientists have warned that progress in the field of genetic medicine depends on the willingness of individuals to submit to genetic tests without fear of discrimination.

In recent years a number of states have enacted genetic privacy laws, but the ACLU believes that a comprehensive federal law is needed to ensure that all Americans are protected from this unacceptable form of discrimination. For this reason, the ACLU has endorsed S. 318, "The Genetic Nondiscrimination in Health Insurance and Employment Act," introduced by Senator Daschle, Chairman Kennedy and others earlier this year.

The ACLU supports S. 318 because it meaningfully addresses the serious threat to civil liberties posed by new genetic technology. It prohibits genetic discrimination in all aspects of employment, including hiring and compensation. It prohibits insurers from restricting enrollment or adjusting fees on the basis of genetic information. And it prohibits both insurers and employers from requiring genetic testing.

During the recent debate on the Patients Bill of Rights (S. 1052), the Senate adopted by voice vote an amendment offered by Senator Ensign on the subject of genetic discrimination. There are several reasons why we believe S. 318 provides superior protection against genetic discrimination than the Ensign amendment.

The most important respect in which S. 318 is preferable is that it bans discrimination by employers as well as health insurers. In contrast, the Ensign amendment only prohibits discrimination by insurers, leaving individuals vulnerable to discrimination in hiring and promotions. Without protections in place in both areas, individuals have reason to fear that their genetic information could be used against them.

Also, the definition of genetic information in the Ensign amendment is narrower than the corresponding definition in S. 318. The Daschle-Kennedy bill protects information gleaned from all genetic tests, even if the test was not administered for the purpose of obtaining genetic information. In contrast, the Ensign amendment explicitly does not cover information derived
from a test administered in order to "detect symptoms, clinical signs, or a diagnosis of disease." Similarly, the Ensign amendment contains an exception that would permit health plans to obtain genetic information "for purposes of diagnosis, treatment or payment" - terms which are not defined in the amendment - while S. 318 contains no such exception.

Finally, S. 318 grants individuals a more complete judicial remedy than the Ensign amendment. Unlike S. 318, the Ensign amendment requires individuals to rely on overworked government agencies to vindicate their rights, at least initially, and limits the penalties levied on violators.

It has been suggested by some that S. 318 may be unnecessary because the Americans with Disabilities Act ("ADA") already prohibits employment discrimination based on genetic information. We agree that Congress intended the ADA to prohibit genetic discrimination. Unfortunately a series of court decisions, notably Sutton v. United Airlines, Inc., 527 U.S. 471 (1999), has narrowly defined the term "disability" under 42 U.S.C. § 12102 (2) and has thereby limited the scope of ADA protections. Individuals who are symptomatic but not disabled can no longer rely on the protection of the ADA, and individuals with a genetic predisposition to an illness that has not yet manifested itself are also likely to fall outside the ADA's protected class.

While we continue to believe that the ADA should be read to prohibit genetic discrimination, we believe it is entirely appropriate for Congress to clarify its intent to outlaw this pernicious practice. At this critical juncture, new legislation is needed to eliminate any ambiguity regarding protections for this most personal of information.

Indeed, whether in the course of this genetic non-discrimination bill or as a separate initiative, Congress should strengthen the ADA by overturning Sutton and similar cases that interpret the Act too narrowly. Congress should make clear that unwarranted discrimination against anyone on the basis of disability is impermissible, whether the victim of discrimination is: (1) actually disabled; (2) symptomatic but not disabled; or (3) genetically predisposed to a disability or medical condition but not symptomatic.

Enactment of a genetic non-discrimination law would be welcome in that it would extend civil rights protection to non-symptomatic individuals, but such a law would inadvertently create a gap in federal law in which discrimination against individuals in the middle category (symptomatic but not disabled) will still be permissible.

In sum, the ACLU believes that Americans should be judged on their actual abilities, not their potential disabilities. No American should lose a job or an insurance policy based on his or her genetic predisposition. We urge Congress to adopt S. 318, the Genetic Nondiscrimination in Health Insurance and Employment Act, and to take such other steps as may be necessary to ensure the privacy of genetic information.
January 29, 2007

Dear Representative:

We write on behalf of the Genetic Information Nondiscrimination in Employment (GINE) Coalition to express our strong concerns with the Genetic Information Nondiscrimination Act of 2007 (H.R. 493). The Senate Health, Education, Labor, and Pensions Committee is scheduled to mark up the Senate version of the bill on Wednesday, January 31, and the House Education and Labor subcommittee on Health, Employment, Labor, and Pensions will consider the issue of genetic discrimination at a hearing on Tuesday, January 30. **We urge you not to cosponsor H.R. 493, and if the Genetic Information Nondiscrimination Act is considered in the House, not to support the bill or similar legislation unless the following concerns are addressed.**

The GINE Coalition is a group of employers, national trade associations, and professional organizations formed to address concerns about workplace discrimination based on employees’ genetic information as well as the confidentiality of that information.¹ The Coalition strongly supports genetic nondiscrimination and confidentiality, and believes that employment decisions should be based on an individual’s qualifications and ability to perform a job, not on characteristics that have no bearing on job performance.

We also believe, however, that any legislation on this issue must be carefully designed to minimize uncertainties, unintended consequences, and unwarranted litigation. To this end, the Coalition, while at times questioning the need for legislation, has worked diligently for several years with Congress and proponents of the Genetic Information Nondiscrimination Act, consistently advocating that any legislation be fair, reasonable, and narrowly drafted.

Foremost among the Coalition’s concerns with the legislation are:

- **Benefits mandate**—The bill would permit plaintiffs to sue an employer for offering health benefits that do not cover treatment for a specific genetic condition (President Clinton signed an Executive Order specifically exempting the federal government from similar suits). Thus, the bill could act as a de facto federal mandate requiring employers to offer health plans covering all treatments for genetic related conditions.

- **Punitive damages for technical and paperwork errors**—Under the bill, employers could face substantial damages, including compensatory and punitive damages, for paperwork violations or for failing to properly distinguish genetic information from other health care information.

¹ Title I of the Genetic Information Nondiscrimination Act addresses issues related to genetics and insurance coverage. Although certain individual Coalition members may have views on Title I, the Coalition’s comments are limited to Title II of the bill.
• **Confusing and inconsistent recordkeeping and technical requirements**—The bill 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. Indeed, in many cases, employers might be required to keep two sets of confidential health care files for employees—one for records with genetic information, one for records with other health care information.

• **Inconsistent state laws**—The legislation does not create a single federal standard, but allows a patchwork of state standards to impose inconsistent requirements.

• **Broad definition of family member**—The bill’s definition of “family member” is too expansive and will increase the amount of frivolous litigation. The bill defines family members as *any* individual related by blood or *any* individual related by blood to a child placed for adoption with the employee no matter how remote the relation. The bill should only cover instances in which information is scientifically proven to reveal patterns of inheritance of genetic conditions and is useful for medical diagnosis of the employee and his or her immediate family.

The attached document expands on each of these points and our other major concerns.

Proponents of the Genetic Information Nondiscrimination Act have argued that legislation is necessary in order to promote genetic testing by giving people more confidence that the results of their genetic tests will not be misused. If Congress is to pass legislation to address this problem, then it should be narrowly tailored to ensure that it does not open the door for excessive and needless litigation and administrative burdens. Unfortunately, even under our existing anti-discrimination laws, most charges filed are without merit (as evidenced by the Equal Employment Opportunity Commission’s statistics, which found absolutely no cause for discrimination in more than 62 percent of charges filed in 2006). Congress should not increase the number of frivolous lawsuits by passing overly broad legislation.

Thank you for your consideration. Please do not hesitate to contact us if you would like to discuss these concerns in greater detail.

Sincerely yours,

The GINE Coalition Steering Committee:

College and University Professional Association for Human Resources  National Retail Federation  National Association of Manufacturers
HR Policy Association  Society for Human Resource Management  U.S. Chamber of Commerce
Major Concerns with Title II of the Genetic Information Nondiscrimination Act

Limit the Scope to Genetic Tests

The driving force for this legislation is not an ongoing practice of discrimination or mishandling of genetic information, but, rather that the fear of possible discrimination may deter employees from availing themselves of genetic tests. Accordingly, the bill only should prohibit employers from discriminating based on genetic tests, not family history that could be – and most times is – completely unrelated to tests. This would greatly minimize the opportunity for unintended consequences and unnecessary litigation under the bill, while also thoroughly addressing the issue which fueled the bill’s creation. It would also greatly reduce the probability that the bill will conflict or complicate compliance with other laws, such as the Americans with Disabilities Act (ADA). If the bill is to include provisions regulating genetic information, then it is imperative that such provisions be consistent with the ADA and HIPAA. Unfortunately, rather than address any possible gaps between the ADA and HIPAA, the bill creates an entirely new regime to regulate medical information and then seeks to eliminate absurd consequences through inadequate exceptions (genetic information obtained through FMLA certification is excepted, but not through sick leave certification, for example).

Damages

Given the lack of genetic discrimination and 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, the bill resorts to jury trials with punitive and compensatory damages, which will necessarily invite additional litigation, as was the case when such damages were made available under other discrimination laws. The courts already are inundated with employment litigation and certainly do not need the additional workload.

One Federal Standard

Any 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 from state to state. 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.

Narrow the Definition of Family Member

If there must be a cause of action based on family history, then it should be of reasonable scope. The bill defines family members as any individual related by blood or any individual related by blood to a child placed for adoption with the employee no matter how remote the relation. This is merely an opportunity for plaintiffs’ attorneys to exploit, and an invitation for frivolous litigation. The bill only should cover situations where the information is scientifically proven to reveal patterns of inheritance of genetic conditions and is useful for medical diagnosis in the employee and his or her immediate family.

An Independent Commission

The bill would require the creation of a commission six years after the bill’s enactment 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.” The Commission, to be known as the Genetic Nondiscrimination Study Commission, is to be housed and funded by the Equal Employment Opportunity Commission (EEOC).

For More Information Contact:
Mike Eastman (meastman@uschamber.com), Michael Layman (mlayman@shrm.org), Jason Straczewski (jstraczewski@nam.org), Josh Ulman (julman@cupahr.org) or Neil Trautwein (trautweinn@nrf.com)
While the Coalition has no objection to the idea of a commission, we do object to tying both its housing and funding to the EEOC. No one would ever suggest that the business trade association or law firm that regularly defended claims made under the bill would be an appropriate source of funding or housing for the Commission. So too, it should be with the EEOC – the agency tasked with prosecuting violations of the bill. Clearly, the EEOC will have its own views on what changes should be made to genetics legislation, and it is unlikely those views would be objective. By tying the Commission’s housing and funding to the EEOC, it is inevitable that the Commission will be largely staffed with former or current EEOC employees – some of whom will have been responsible for prosecuting claims under the bill. To prevent this undue influence, the Commission should be funded and housed independent of the EEOC.

Expanded Commission & Sunset

Any genetic nondiscrimination legislative proposal should contain a mechanism to ensure that public policy keeps pace with future scientific advances. Given the rapid evolution in the field, legislation drafted now is unlikely to anticipate developments in genetic science that could occur even in the near future. As demonstrated by state experience – where several states were compelled to revisit their original legislation - unintended consequences can sometimes force the legislature to rewrite legislation within just a few years. Thus, the Genetic Nondiscrimination Study Commission should study and report on all aspects of the bill – as it name implies – not just disparate impact. The bill should also provide for a sunset date, at which time Congress may consider new issues related to genetic discrimination raised by the Commission and adjust the legislation accordingly. Such a model creates a powerful incentive for Congress to revisit the law and make appropriate modifications.

Direct Threat - Protecting Employees and the Public

The ADA, Title VII of the Civil Rights of 1964, and other discrimination laws recognize that there can be rare cases where an employer has a legitimate reason to make employment decisions based on information that would otherwise be protected. Courts have interpreted these exceptions extremely narrowly but have recognized that employers can have valid reasons for such policies. For example, under the ADA, a health condition likely to cause uncontrollable seizures could properly be considered a “direct threat” to safety if the employee were a bus driver, thus justifying an employment decision that would otherwise be unlawful. A similar narrow exception should exist for genetic discrimination. For example, if an employee has a genetic predisposition for a high chance of developing a severe disease by working in proximity to a chemical that might only pose a minor risk to others, then employers should be able to make employment decisions based on this information. Thus, we propose adding the following language, which mirrors that of the ADA: “Nothing in this bill shall be construed to prohibit an employer from requiring that an individual not pose a direct threat to the health and safety of other individuals in the workplace.”

Choice of Remedies

In the only recorded case where an employer was accused of engaging in genetic testing and genetic discrimination, the individual plaintiffs filed claims against their employer with the EEOC, which, in turn, sued the employer under the ADA. The agency successfully settled the case for $2.2 million. Thus, if the bill is enacted, individuals and the EEOC will be empowered to bring suit against an employer on the same facts under both the bill and the ADA.

In the 107th Congress, the original sponsors of the bill introduced similar legislation (S. 1995) that included an “election of remedies,” under which a plaintiff could sue under the genetics bill or the ADA, but not both. That provision is not in the bill. It should be re-inserted in the bill in order to prevent multiple lawsuits, double recovery and unnecessarily complex litigation.

For More Information Contact:
Mike Eastman (meastman@uschamber.com), Michael Layman (mlayman@shrm.org), Jason Straczewski (jstraczewski@nam.org), Josh Ulman (julman@cupahr.org) or Neil Trautwein (trautweinn@nrf.com)
Information Discrimination

How laws protecting genetic privacy can do more harm than good.

Ronald Bailey | May 16, 2001

The specter of genetic discrimination haunts the debate over health insurance in America. Now that the complete human genome is available and more than 400 tests are available for various genetic disorders, the issue is rising quickly to the top of the public agenda. There have been documented cases where people have lost their health insurance once the results of a genetic test became known. Surveys show that a substantial number of people are refusing to take genetic tests at least partly out of fear that they may lose their health insurance coverage if the results show that they have a genetic problem. In an attempt to quell such anxiety, 37 states have passed laws limiting insurers' access to various types of genetic information.

In February, Rep. Louise Slaughter (D-N.Y.) introduced legislation in the U.S. House that would outlaw genetic discrimination in employment and insurance. The bill, which boasts 225 cosponsors, has been endorsed by over 100 organizations, including the March of Dimes, the National Breast Cancer Coalition and the American Civil Liberties Union. Sen. Tom Daschle (D-S.D.) has introduced a similar bill in the Senate. Whatever their intentions, such measures have the effect of making insurance more expensive and of slowing down the sort of research that will someday make genetic problems minor inconveniences.

Mark Hall, a law professor at Wake Forest University, points out that genetic testing brings two different conceptions of "fairness" into conflict. Many people, notes Hall, believe that "it is fundamentally unfair and morally wrong to penalize people due to their bad luck in the genetic lottery." But many people also believe that it's not fair "to charge the genetically advantaged more for their insurance in order to lower costs for the genetically disadvantaged." After all, says Hall, "the advantaged are not responsible for the disadvantaged's misfortune."

This much is certain: The business of insurance requires that underwriters accurately assess the risks that they are insuring against. That's the only way they can charge the proper premiums to cover the payoffs that they must make to the people they insure. Clearly, predictive information from increasingly accurate genetic tests is relevant to assessing risks. Yet two-thirds of states have made it difficult, if not downright impossible, to do so.

Preventing insurance companies from gaining access to the information provided by genetic tests leads to the problem of adverse selection. Adverse selection occurs when there is an asymmetry of information. In this case, people whose genetic tests indicate that they are at high risk of becoming ill or dying prematurely are likely to load up on gold-plated insurance coverage. Because insurers won't know the results of the tests, the premiums they charge will not cover the cost of taking care of high-risk customers.

In essence, genetic privacy laws allow high-risk insurees to lie about their health in order to get more money. This means that healthier customers will have to be charged more to pay for their high-risk counterparts. This situation can set off an adverse selection spiral in which low-risk clients flee the higher premiums and high-risk clients flock to buy the insurance. As premiums rise to cover the unhealthy clients, fewer and fewer people can afford insurance.
Are purchasers of insurance really all that savvy? Absolutely. In 1992, New York State passed a "community rating" law in an effort to bring down insurance prices. The New York law forbade insurers from offering lower rates to companies with younger, healthier employees--the effect of which was to increase rates for those workers. Faced with higher rates, large numbers of younger workers simply dropped their coverage, leaving relatively unhealthy oldsters to fend for themselves. The result was higher rates and fewer people covered by health insurance. The same problem also plagued recent attempts to do the same with the Federal Employees Health Benefit Plan and the California Public Employees Retirement System.

Keeping insurers from getting access to genetic tests is all the more misguided since the information could, in fact, lower the average price of insurance. How? By reducing the amount of unknown risk faced by insurers. Of course, it's indisputable that some people with high risks would have to pay considerably more. But that problem can be addressed on its own terms. One possible solution would be to let patients buy "genetic test insurance" to insure themselves against any unknowns before they take particular genetic tests.

Tom Miller, director of Health Policy Studies at the Cato Institute, suggests another: Insurers could offer a two-tier insurance product. Customers could purchase a long-term, basic insurance component to cover their risks at the time of initial purchase. The second tier would be a savings component in which the insured would deposit premiums that are invested over time. If the insured's health risks go up, he could draw down his invested savings to pay for higher premiums. Any money left over in the savings component could be passed along to heirs, or perhaps withdrawn at retirement. Right now, however, insurers and their customers are discouraged by public policy from seeking innovative solutions to how to handle genetic information.

Adding to the confusion is the current state of genetic therapy. Today, genetic tests can often predict the likelihood of the onset of a disease, such as Alzheimer's or Huntington's, for which there are not yet effective treatments. In a sense, our problem is that we are living in a time when our ability to diagnose genetic problems far outstrips our ability to cure or remediate those same problems. We will eventually move from a diagnostic era to a therapeutic one, a time when patients will be eager to take genetic diagnostic tests because physicians will be able to offer effective, preventive treatments for their disorders.

"Concerns about the negative consequences of genetic information will begin to dissipate as we begin to close the gap between our ability to diagnose and predict and our ability to treat," notes Roberta Berry, a visiting law professor at the University of Notre Dame.

In the meantime, though, laws designed to protect genetic test results are fanning fears of genetic discrimination and making it more difficult to gather the sort of data (and attract the sort of investment) that will help researchers solve genetic problems. In trying to protect individuals, legislators are instead delaying the dawning of that therapeutic age, and causing people to suffer needlessly.
GROUP 4: Employers’ Coalition for the Right to Screen

The following article has been edited from the site below to support employers right to genetic screening/testing.
[ http://www.scu.edu/ethics/publications/iie/v4n2/genes.html ]

READ MY GENES:
GENETIC SCREENING IN THE WORKPLACE

By Claire Andre and Manuel Velasquez

Few employment practices have stirred as much controversy as employment testing. From psychological questionnaires to urine samples, the devices used by employers to screen, select, and place workers have been challenged by civil rights groups and courts alike. But none is likely to spark more debate than genetic tests. These tests can detect the presence of genetic abnormalities in healthy individuals that may place those individuals at increased risk for developing certain diseases. In the workplace, such tests can be used to screen job applicants and employees who, because of their genetic makeup, may be more likely to develop diseases if exposed to certain worksite substances, such as chemicals or radiation.

Research to date has identified about fifty genetic disorders thought to increase a person's susceptibility to the toxic or carcinogenic effects of environmental agents. Individuals with the sickle cell trait, for example, may be at increased risk for sickle cell anemia if exposed to carbon monoxide or cyanide. Exposure to lead or benzine can be especially hazardous to the health of people with the thalassemia gene.

Presently, few companies report using genetic tests; the tests currently available can identify only a small number of relatively rare diseases, are costly to perform, and difficult to administer. But advances in genetic research and technology, accelerated by the 15-year, $3 billion federally-funded Human Genome Project which aims to decode the genetic makeup of humans, are likely to soon make available simplified, less costly tests able to detect a wide range of common genetic disorders, including those not necessarily associated with worksite exposure, such as predisposition to heart disease, cancer, and manic depression. As such tests become available, it is anticipated that interest in testing will grow.

Genetic screening is often advocated as a means of significantly reducing the incidence of occupational disease. Employers can use information obtained from genetic testing to ensure that prospective or current employees are not placed in environments that might cause them harm. But critics of this emerging technology maintain that screening violates workers rights and increases racial and ethnic discrimination in the workplace, charges that take on added force with the availability of tests for traits not associated with work-related diseases. Should genetic screening be allowed in the workplace?
Those who support genetic screening claim that screening would benefit employees, employers, and society as a whole. According to one report, 390,000 workers contract disabling occupational diseases each year; 100,000 of these workers die. With the information obtained through genetic screening, workers could avoid work environments that would be hazardous to their health, sparing workers and their families the physical, emotional, and financial costs of disabling diseases and premature death.

Employers too would benefit from genetic screening. In 1981, the Bureau of labor statistics reported that occupational illness costs private sector employers 850,000 lost workdays. Litigation over illnesses associated with hazardous worksite substances also impose heavy costs on employers. By reducing occupational disease, genetic screening could reduce the costs of lowered productivity, excess absenteeism, and high employee turnover, as well as the cost associated with workers' compensation payments, health insurance, and liability for occupational disease.

The lowered incidence of work-related diseases resulting from genetic screening would also benefit society as a whole by reducing the health care costs covered by Medicare and Medicaid, public assistance, and social security payments.

Supporters of screening also argue that, contrary to the critics' charges, genetic screening does not violate the rights of employees. Those job applicants or employees who object to being screened are free to forego testing and seek employment elsewhere. Furthermore, employers have an interest in maintaining a healthy and productive workforce and a legitimate right to adopt policies, such as genetic screening, that protect this interest. In fact, if an employer fails to test a high-risk worker who then develops a disease as a result of exposure to substances in the workplace, that employer could be held negligent. To protect their interests, then, employers should be free to screen such workers.

Still others defend genetic screening on the grounds that all individuals have a basic right not to be harmed, and employers thus have a duty to provide a safe workplace. In general, the safety of a workplace is ensured by an employer's compliance with regulations governing exposure to hazardous substances. But in cases involving individuals who are hypersensitive to such substances where it isn't economically feasible to eliminate those substances, genetic screening ought to be allowed, if not mandated.

Finally, it is argued, screening for genetic traits promotes the freedom of persons to make informed decisions concerning their own welfare. For an employee, a free choice about the work he or she performs requires information about job-related health risks--information that could be readily obtained through genetic tests.

As researchers unravel the genetic codes responsible for diseases, we are wise to attend to the ethical issues raised by their discoveries. In the case of genetic screening, such a task will require that we carefully weigh the potential harms and benefits of screening, the values we place on privacy and justice, and society's interest in maintaining a healthy and productive workforce.
GENETIC TESTING BY EMPLOYERS

The following article has been edited from the site below to support employers right to genetic screening/testing.

INTRODUCTION

Over the next 15 years, under the auspices of the federal government's "human genome project", scientists will try to map in detail each of the human cell's estimated 100,000 genes. The knowledge derived from the project will enable physicians to detect an increasing number of diseases and predispositions for disease. It is expected that researchers will identify genes that contribute to the development of Alzheimer's disease, alcoholism, coronary artery disease, the different cancers and virtually every other illness. In addition to enhancing the ability of physicians to diagnose disease, the knowledge from the genome project will result in better preventive and therapeutic measures.

Potential applications of information gained from the human genome project extend well beyond the setting of medical care. Employers, insurers and law enforcement agencies all will have uses for genetic testing techniques. In many cases, these uses will provide important social benefits. DNA fingerprinting can establish with greater certainty the identity of a criminal; it can also exonerate the innocent defendant.

However, our past experiences with genetic and other medical testing suggest that abuses may occur.

Some companies may have restricted employment opportunities of individuals who carry the sickle cell trait even though there was no scientific basis for the restrictions. In addition, employment discrimination has occurred repeatedly against individuals because of their medical problems. Previously, irrational fears led employers to deny jobs to patients with cancer or epilepsy. Individuals with HIV infection continue to be victims of employment discrimination.

In this report, the Council will address the use of genetic testing by employers to identify employees (or potential employees) who are at risk for developing certain diseases. Genetic testing by employers will involve the participation of physicians. This report will propose guidelines to help physicians assess when their participation in genetic testing by employers is appropriate and does not result in unwarranted discrimination against individuals with genetic abnormalities. The Council's guidelines are summarized in an opinion at the conclusion of the report.
WORKPLACE TESTING

Employers will have a number of potential justifications for genetic testing in the workplace. In some cases, there may be an argument in favor of testing for public health reasons. Companies have expressed concern about the possibility of an employee's genetic susceptibility to illness from exposure to a chemical or other substance in the workplace. In addition, employers may not want to hire individuals with certain genetic risks for jobs that bear on the public's safety. Other justifications are based not on concerns about health but on concerns about costs, specifically the costs to the company of hiring workers with a genetic risk of disease. Individuals who have a heightened risk for certain illnesses may be less attractive as employees; on average, they may be able to spend fewer years in the work force, and they may impose greater health care costs on the employer.

Since the acceptability of genetic testing turns on the purposes for which the testing is proposed, each of the proposed justifications for testing will be considered separately.

1. Future Unemployability. Employers may be reluctant to hire individuals who have a genetic predisposition for developing a disabling illness like cancer or coronary artery disease because these individuals may become prematurely unable to work. By excluding those at risk for becoming unable to work, employers may be able to lower their costs of recruitment and training.

2. Increased Health Care Costs. Employers may not want to hire individuals with a predisposition for cancer, Alzheimer's disease or other illnesses because these individuals might impose higher health care costs on the employer.

3. Public Safety. In some cases, employers may want to use genetic tests to protect the public's safety. For example, employers of physicians or airline pilots may want to test for the gene that contributes to the development of Alzheimer's disease when such a test exists.

While ensuring the health of employees whose work bears on public safety is an important responsibility of employers, genetic testing is not an appropriate tool for meeting that responsibility. As when used for other purposes, genetic tests will have poor predictive value when used to identify workers who might pose risks to public safety. Employers must show that there is a significant or reasonable likelihood of harm to others from having a person with a genetic risk of disease employed before the person can be excluded from the workplace. Genetic tests are not only generally inaccurate when used for public safety purposes, they are also unnecessary.

4. Susceptibility to Workplace Exposures. Since at least the 1960s, there has been interest in screening workers for genetic susceptibility to injury from chemicals or other substances in the workplace. Some occupational health experts have argued that genetic tests can be used to identify workers who are particularly at risk for injury from workplace toxins. In fact, black employees have been screened for the presence of sickle
cell trait because of concern that exposure to nitro or amino compounds would result in sickling of the blood cells. Male workers have been screened for the sex-linked genetic abnormality of glucose-6-phosphate dehydrogenase (G6PD) deficiency because of concern that exposure to oxidizing chemicals would precipitate hemolytic anemia. Genetic screening has also been conducted to identify workers with alphal-antitrypsin deficiency on the ground that respiratory irritants might cause chronic obstructive lung disease.

There may be a very limited role for genetic testing in the exclusion from the workplace of workers who have a genetic susceptibility to occupational illness. At a minimum, several conditions would have to be met:

a. The disease develops so rapidly that serious and irreversible illness would occur before monitoring of either the worker's exposure to the toxic substance or the worker's health status could be effective in preventing the harm.

b. The genetic testing is highly accurate with sufficient sensitivity and specificity to minimize the risk of false negative and false positive test results.

c. Empirical data demonstrate that the genetic abnormality results in an unusually elevated susceptibility to occupational illness.

d. It would require undue cost to protect susceptible employees by lowering the level of the toxic substance in the workplace. The costs of lowering the level of the substance must be extraordinary relative to the employer's other costs of making the product for which the toxic substance is used. Since genetic testing with exclusion of susceptible employees is an alternative to cleaning up the workplace. The costs of lowering the level of the substance must also be extraordinary relative to the costs of using genetic testing.

e. Testing must not be performed without the informed consent of the employee or applicant for employment.


“DNA has also been culturally endowed with a power and significance exceeding that of other medical information ... genetic information can radically change the way people view themselves ... as well as the way that others view them.”

The future diary metaphor best conveys the private nature of genetic information itself. Our future medical status is not determined solely by genetics, any more than our past diaries are the only source for our personal understanding of the past (or even necessarily reflect it). DNA information, like a diary, however, is a uniquely private part of ourselves.

An individual’s DNA can also reveal information about risks and traits that are shared with genetic relatives, as well as being used to prove relationships. An individual’s DNA has the paradoxical quality of being unique to that individual yet shared with others. Even if one believes that the DNA-sequence information extracted from an individual’s DNA is more sensitive than other medical information, this says nothing about the need to protect the DNA molecule itself. In this regard, we think it is useful to view the DNA molecule as a medical record in its own right. Having a DNA sample from an individual is like having medical information about the individual stored on a computer disk, except in this case the information is stored as blood or as other tissue samples. Like the computer disk, the DNA sequence can be “read” by the application of technology. So, regardless of the rules developed to control the use of genetic information when it is recorded in traditional paper and electronic medical records, separate rules are also needed to regulate the collection, analysis, storage and release of DNA samples themselves. This is because once a physician or researcher has a DNA sample, there is no practical need for further contact with the individual from whom the DNA was obtained, and DNA tests could be done on the stored sample (and thus on the individual) in their absence. Some of these tests might as yet be undeveloped but all will produce new genetic information about the individual.

DNA has also been culturally endowed with a power and significance exceeding that of other medical information. Much of this significance is undoubtedly misplaced, but can be justified in so far as genetic information can radically change the way people view themselves and family members, as well as the way the others view them. The history of genetic testing, particularly in relation to rare monogenic diseases, such as Huntington disease, provides us with examples of this impact. Studies of individuals who have undergone testing in clinical settings show the changes in self-perception caused by positive, as well as negative, test results.

Individuals with a decreased risk of having a genetic disease have reported difficulty in setting expectations for their personal and
developing a disease. Consequently, it is presumed that they were at high risk for making reproductive decisions based on the future. Adjustments seem to have been professional lives in a more open-ended future. Adjustments seem to have been particularly difficult for those who have already made reproductive decisions based on the presumption that they were at high risk for developing a disease. Consequently, it is good policy to provide genetic counselling before and after testing. And in the interests of protecting the privacy of children and adolescents, some institutions have also adopted a policy of refusing parental requests to test children for late-onset diseases when no medical intervention is available to prevent or alleviate the genetic condition. Perhaps the principal reason why neither DNA-sequence information nor DNA samples themselves have been afforded special privacy protection is the strongly held view of many genetic researchers and biotechnology companies that privacy protections would interfere with their work. One court in the United States has addressed whether constitutional rights to privacy are implicated by genetic testing. In Norman-Bloodsaw v. Lawrence Berkeley Laboratory, employees of a research facility owned and operated by state and federal agencies alleged that non-consensual genetic testing by their employers violated their rights to privacy. Holding that the right to privacy protects against the collection of information by illicit means, as well as unauthorized disclosures to third parties, the court stated "One can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up." DNA research and privacy Now that the human genome has been sequenced, attention is shifting to research on genetic variation that is designed to locate genes and gene sequences with disease-producing or disease-prevention properties. Some researchers have already taken steps to form partnerships and create large DNA banks that will furnish the material for this research. Others want to take advantage of the large number of stored tissue samples that already exist. In the United States, for example, the DNA of about 20 million people is collected and stored each year in tissue collections ranging from fewer than 200 to more than 92 million samples. Collections include Guthrie cards, on which blood from newborns has been collected for phenylketonuria screening since the 1960s, paraffin blocks used by pathologists to store specimens, blood-bank samples, forensic specimens and the US military's bank of samples for use in identifying bodily remains.

Several factors have contributed to the proliferation of DNA banking: the relative ease with which DNA can be collected, its coincidental presence in bodily specimens collected for other reasons and its immutability. Regardless of the original purposes for storing specimens, however, as the ability to extract information from DNA increases and the focus of research shifts to genetic factors that contribute to human diseases and behaviours, repositories that contain the DNA of sizeable populations can be "gold mines" of genetic information. So, it is not surprising that there is considerable interest on the part of biomedical researchers, companies that market genomic data and the pharmaceutical industry, to stake claims on these informational resources and to exploit them for their own purposes.

Commercial enterprises, as well as academic researchers, have equally strong interests in making it relatively easy to access DNA samples that can be linked to medical records for research purposes. Representatives of these constituencies have been vocal in arguing that requirements for informed consent and the right to withdraw data from ongoing research projects would greatly hamper their research efforts. When US federal rules apply to such research — as is the case with federally funded projects and any projects related to obtaining approval from the US Food and Drug Administration to market drugs or devices — the local Institutional Review Board (IRB) must approve the research protocol. These boards should not waive federal research requirements on informed consent (nor exempt researchers from them) except when the IRB determines that the research will be conducted in such a way that the subjects cannot be personally identified. If existing research rules were consistently and diligently applied perhaps we could confidently state that the privacy of research subjects is adequately protected. Today, however, such confidence would be misplaced.

These privacy and consent issues are not limited to the United States. The most internationally discussed DNA-based project has been deCODE Genetics in Iceland, a commercial project that has been opposed by the Iceland Medical Association, among others, for 'ethical shortcuts', such as 'opt-out' provisions that presume an individual's consent (see below). The deCODE project, which has been endorsed by two acts of the Iceland parliament, involves the creation of two new databases: the first containing the medical records of all Iceland citizens, and the second containing DNA samples from them (a third database, of genealogical records, already exists). deCODE intends to use these three databases in various combinations to identify genetic variations that could be of pharmaceutical interest. The chief ethical issues raised by this project are as follows: first, the question of informed consent for inclusion of personal medical information in the database, which is at present included under the concept of presumed consent — this requires individuals to actively opt out of the research if they do not want their information in the database; second, informed consent
### Box 2 | Assessing genetic privacy

Laws or policies that purport to protect genetic privacy, at a minimum, should do the following:

- **Recognize individual genetic rights, particularly:**
  - the right to determine if and when their identifiable DNA samples are collected, stored or analyzed;
  - the right to determine who has access to their identifiable DNA samples;
  - the right of access to their own genetic information;
  - the right to determine who has access to their genetic information;
  - the right to all information necessary for informed decision-making about the collection, storage and analysis of their DNA samples and the disclosure of their private genetic information.

- **Limit parental rights to authorize the collection, storage, or analysis of a child’s identifiable DNA sample so as to preserve the child’s future autonomy and genetic privacy.**

- **Prohibit unauthorized uses of individually identifiable DNA samples, except for some uses in solving crimes, determining paternity or identifying bodily remains.**

- **Prohibit disclosures of genetic information without the individual’s explicit authorization.**

- **Strictly enforce laws and institutional policies.**

- **Provide accessible remedies for individuals whose rights are violated.**

- **Institute sufficient penalties to deter and punish violations.**

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Policy recommendations

We have argued in the past that a principal step to achieving genetic privacy would be the passage of a comprehensive federal genetic privacy law. The primary purpose of such a law is to give individuals control over their identifiable DNA samples and the genetic-sequence information extracted from them. The model we suggest provides that individuals have a property interest in their own DNA — and that this property interest gives them control over it. Control could also, however, be obtained by requiring explicit authorization for the collection and use of DNA, including its research and commercial use. We believe that in the absence of authorization no one should know more about an individual’s genetic make-up than that individual chooses to know about himself and, that an individual should also know who else knows (or will know) their private genetic information.

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### Risks of disclosure of personal genetic information

Risks of disclosure of personal genetic information are so high that some prominent genetic researchers, including Francis Collins and Craig Venter, have suggested concentrating not on privacy rules, but rather on anti-discrimination legislation that is designed to protect individuals when their genetic information is disclosed, and when insurance companies, employers or others want to use that information against them. We agree that anti-discrimination legislation is desirable, but it does not substitute for privacy rules that can prevent the genetic information from being generated in the first place without the individual’s informed authorization.

This point is well illustrated by a law recently enacted in Massachusetts — a state with a population more than 20 times larger than the population of Iceland — that has been mistakenly characterized in the US press as ‘a sweeping set of genetic privacy protections’. Under this new law, written informed consent is a prerequisite to predictive (but not diagnostic) genetic testing and to disclosing the results of such tests by entities and practitioners that provide health care. The law also limits the uses that insurers and employers can make of genetic information. However, it places no limitations on how researchers and biotechnology companies that engage in projects requiring the use of identifiable samples and identifiable genetic information conduct their activities. Apparently, those who drafted the statute believed that they need not be concerned about protecting research subjects because research with human subjects is regulated by the federal government, failing to recognize that many activities of genomic companies do not fall under the jurisdiction of the federal regulations.

One proposal to deal with privacy issues and individual control over genetic information is to have DNA samples and medical records collected by a ‘third-party broker’ of genetic information who would then, with the informed consent of the individual, make this information available to researchers in a coded form. A for-profit company, First Genetic Trust, has been formed in the United States to try out this model. Individuals are solicited through the Internet to participate in the Trust and all communication with those who participate, including consent to new studies, will take place over the Internet. The purpose of the Trust is to assure individuals that no one would be able to use their DNA, or their personal...
medical information associated with it, without the individual’s authorization. Some might criticize this approach as going too far in protecting participants, noting that consent is not generally necessary for IRB-approved research that does not involve identifiable data. Regardless of the fact that First Genetic Trust itself will not be engaged in research, as long as data held by the Trust can be linked to individuals, we think authorization should be required and that proposals such as this one are a step in the right direction.

Whether arrangements such as these will lead to significant public participation in genetic research remains to be seen. Despite the availability of tests for genes that predispose individuals to several diseases, including Huntington disease and some forms of breast and colon cancers, the number of people who choose to undergo clinical genetic testing has remained far below the expectations of the companies that sell tests and of the physicians who believe their patients would benefit from them. Why is the public, which is on the one hand fascinated with each advance in mapping the genome, the identification of particular genes and the possible association of a gene with particular human characteristics, simultaneously reticent to undergo genetic testing? Explanations that individuals give for avoiding genetic tests include fear of discrimination, concern over the impact on family members, lack of effective treatments and preference for uncertainty about the future.41,42 Privacy protections have little, if any, impact on attitudes towards the future. Nevertheless, by regulating the creation, maintenance and disclosure of information, they can reduce privacy risks and provide some reassurance to those who might not otherwise participate in genetic research or clinical testing.

Once individual interests in privacy and in being treated fairly on the basis of genetic information have been addressed, only property issues remain. Individuals can be thought of as having a property right in their DNA, including, among other things, the right to restrict others from ‘trespassing’ on their property without permission.43 One US state, Oregon, incorporated an individual’s right of ownership of DNA into its laws in 1995 (Ref. 48). Objections that this law would restrict others from using DNA into its laws in property rights in their DNA to researchers, and are much more likely to do so if their privacy can be guaranteed (as it can be if identifiers are not retained).

DNA can rightly be seen as containing uniquely personal, powerful and sensitive information about individuals and their families. Some individuals want to know as much of this information about themselves as possible, and might be willing to share this information with their families and others. Others would rather remain ignorant about their own genetic make-up, and thus their risks for future illnesses, or at least to keep others ignorant of such information. We believe that individual choices are best served by policies that place primary control over an individual’s DNA and genetic information in the hands of individuals. We also believe privacy protections will prove as necessary for the future of genetic research and clinical applications, as they will be for the future of e-commerce. We believe that the sort of adequate genetic privacy protections are in place, the better it will be for all of us.

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Links

DATABASE LINKS Huntington disease | phenylketonuria

FURTHER INFORMATION European Data Protection Directive | US Food and Drug Administration | deCODE Genetics | First Genetic Trust | UK Population Biomedical Collection | Medical Research Council | the Welcome Trust | Ardisia Corporation | Autogen Ltd


Acknowledgements

The authors thank their colleague, Leonard H. Glantz, for his contribution to formulating the policy recommendations presented in this article.
On May 21st, President Bush signed into law the Genetic Information Nondiscrimination Act (GINA), which prohibits U.S. insurance companies and employers from discriminating on the basis of information derived from genetic tests. GINA passed both houses of Congress with a vote in the U.S. House of Representatives of 414 to 1. The bill had passed in the House twice before, most recently last year when the vote was 420 to 3. The U.S. Senate unanimously passed the current bill after compromises were reached on areas of disagreement that had held up its passage for several months.

GINA protects Americans from discrimination based on information derived from genetic tests. It forbids insurance companies from discriminating through reduced coverage or pricing and prohibits employers from making adverse employment decisions based on a person’s genetic code. In addition, insurers and employers are not allowed under the law to request or demand a genetic test.

A 2001 study by the American Management Association showed that nearly two-thirds of major U.S. companies require medical examinations of
new hires. In addition, 14% conduct tests for susceptibility to workplace hazards, 3% for breast and colon cancer, and 1% for sickle cell anemia; 10% collect information about family medical history.

“Because of this legislation, Americans will be free to undergo genetic testing for diseases such as cancer, heart disease, diabetes, and Alzheimer’s without fearing for their job or health insurance,” said House speaker Nancy Pelosi (D-Calif.) in a statement.

Increased genetic testing makes it more likely that researchers will come up with early, lifesaving therapy for a wide range of diseases with hereditary links, lawmakers said. Genetic testing also will help doctors catch problems early, perhaps leading to preventive treatment and lower costs.

For More Information

- Genetic Information Nondiscrimination Act of 2008 (Public Law 110-233)
- Genetic Alliance: GINA Coverage
- THOMAS: HR 493 Genetic Information Nondiscrimination Act of 2007
- Wired: Genetic Protections Skimp on Privacy, Says Gene Tester, May 2008

Quick Links for this page:

- Federal genetics policy
- State genetics policies
- Pre-GINA federal antidiscrimination laws and how they apply to genetics
- Recommendations for future legislation
- Why legislation is needed
- Cases of genetic discrimination
- More information

I. Federal Policy History
There are two primary pieces of federal legislation that directly apply to genetics nondiscrimination: The Genetic Information Nondiscrimination Act of 2008 and the 2000 Executive Order to prohibit discrimination in federal employment based on genetic discrimination.

**Genetic Information Nondiscrimination Act (GINA)**

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For More Information

- [White House Press Release, May 21, 2008](#)
- [Nature: Genetics bill cruises through Senate, April 30, 2008.](#)
- [Genetic Alliance: GINA Coverage](#)
- [THOMAS: HR 493 Genetic Information Nondiscrimination Act of 2007](#)
- [Wired: Genetic Protections Skimp on Privacy, Says Gene Tester, May 2008](#)

**Executive Order Protecting Federal Employees**

On February 8, 2000, U.S. President Clinton signed an *executive order* prohibiting every federal department and agency from using genetic information in any hiring or promotion action. This executive order, endorsed by the American Medical Association, the American College of Medical Genetics, the National Society of Genetic Counselors, and the Genetic Alliance

- *Prohibits* federal employers from requiring or requesting genetic tests as a condition of being hired or receiving benefits. Employers cannot request or require employees to undergo genetic tests in order to evaluate an employee's ability to perform his or her job.
- *Prohibits* federal employers from using protected genetic information to classify employees in a manner that deprives them
of advancement opportunities. Employers cannot deny employees promotions or overseas posts because of a genetic predisposition for certain illnesses.

- **Provides** strong privacy protections to any genetic information used for medical treatment and research. Under the EO, obtaining or disclosing genetic information about employees or potential employees is prohibited, except when it is necessary to provide medical treatment to employees, ensure workplace health and safety, or provide occupational and health researchers access to data. In every case where genetic information about employees is obtained, it will be subject to all Federal and state privacy protections.

### II. State Policy History

States have a patchwork of genetic-information nondiscrimination laws, none of them comprehensive. Existing state laws differ in coverage, protections afforded, and enforcement schemes. Some of the first state laws enacted to address this issue prohibited discrimination against individuals with specific genetic traits or disorders. Other state laws regulate both the use of genetic testing in employment decisions and the disclosure of genetic test results. These state laws generally prohibit employers from requiring workers and applicants to undergo genetic testing as a condition of employment. Some states permit genetic testing when it is requested by the worker or applicant for the purpose of investigating a compensation claim or determining the worker's susceptibility to potentially toxic chemicals in the workplace. These statutes often require the worker to provide informed written consent for such testing, contain specific restrictions governing disclosure, and prevent the employer from taking adverse action against the employee.

More information is available from the National Conference of State Legislatures

- **State genetics laws** by specific topic and state
- **Genetics Legislation Database**: Contains information on genetics bills considered in state legislatures from 2004 to present.
- **Genetic Technologies Project**
- Report: **Genetics: A Snapshot for State Legislatures**
- **Genetics policy briefs**
- Article: **Plunging into the gene pool**, March 2007
- **State genetics reports**

See also the NIH NHGRI **Policy and Legislation Database**
III. Pre-Gina Federal Anti-Discrimination Laws and How They Apply to Genetics

Although not fully tested in the courts, some believe that parts of existing nondiscrimination laws could be interpreted to include genetic discrimination. Here is a brief overview of these laws and how they apply to genetics.

Americans with Disabilities Act of 1990 (ADA)
The most likely current source of protection against genetic discrimination in the workplace is provided by laws prohibiting discrimination based on disability. Title I of the Americans with Disabilities Act (ADA), enforced by the Equal Employment Opportunity Commission (EEOC), and similar disability-based antidiscrimination laws such as the Rehabilitation Act of 1973 do not explicitly address genetic information, but they provide some protections against disability-related genetic discrimination in the workplace.

- Prohibits discrimination against a person who is regarded as having a disability.
- Protects individuals with symptomatic genetic disabilities the same as individuals with other disabilities.
- Does not protect against discrimination based on unexpressed genetic conditions.
- Does not protect potential workers from requirements or requests to provide genetic information to their employers after a conditional offer of employment has been extended but before they begin work. (Note: this is a heightened concern because genetic samples can be stored.)
- Does not protect workers from requirements to provide medical information that is job related and consistent with business necessity.

In March 1995, the EEOC issued an interpretation of the ADA. The guidance, however, is limited in scope and legal effect. It is policy guidance that does not have the same legal binding effect on a court as a statute or regulation and has not been tested in court. According to the interpretation,

- Entities that discriminate on the basis of genetic predisposition are regarding the individuals as having impairments, and such individuals are covered by the ADA.
- Unaffected carriers of recessive and X-linked disorders, individuals with late-onset genetic disorders who may be identified through genetic testing or family history as being at high risk of developing the disease are not covered by the ADA.
Health Insurance Portability and Accountability Act of 1996 (HIPAA)
The Health Insurance Portability and Accountability Act (HIPAA) applies to employer-based and commercially issued group health insurance only. HIPAA is the only federal law that directly addresses the issue of genetic discrimination. There is no similar law applying to private individuals seeking health insurance in the individual market.

- Prohibits group health plans from using any health status-related factor, including genetic information, as a basis for denying or limiting eligibility for coverage or for charging an individual more for coverage.
- Limits exclusions for preexisting conditions in group health plans to 12 months and prohibits such exclusions if the individual has been covered previously for that condition for 12 months or more.
- States explicitly that genetic information in the absence of a current diagnosis of illness shall not be considered a preexisting condition.
- Doesn't prohibit employers from refusing to offer health coverage as part of their benefits packages.

For more information see HIPAA information from US Department of Health and Human Services (HHS) or the HIPAA Advisory Web site.

HIPAA National Standards to Protect Patients' Personal Medical Records, Dec. 2002
This regulation would protect medical records and other personal health information maintained by health care providers, hospitals, health plans and health insurers, and health care clearinghouses. The regulation was mandated when Congress failed to pass comprehensive privacy legislation (as required by HIPAA) by 1999. The new standards: limit the nonconsensual use and release of private health information; give patients new rights to access their medical records and to know who else has accessed them; restrict most disclosure of health information to the minimum needed for the intended purpose; establish new criminal and civil sanctions for improper use or disclosure; and establish new requirements for access to records by researchers and others. They are not specific to genetics, rather they are sweeping regulations governing all personal health information.

For more on the standards, see:

- Administration Simplification Under HIPAA: National Standards
Title VII of the Civil Rights Act of 1964
An argument could be made that genetic discrimination based on racially or ethnically linked genetic disorders constitutes unlawful race or ethnicity discrimination.

- Protection is available only where an employer engages in discrimination based on a genetic trait that is substantially related to a particular race or ethnic group.
- A strong relationship between race or national origin has been established for only a few diseases.

IV. Recommendations for Future Legislation

Insurance Discrimination

In 1995, the NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications of Human Genome Research (ELSI Working Group) and the National Action Plan on Breast Cancer (NAPBC) developed and published the following recommendations for state and federal policy makers to protect against genetic discrimination (*Science*, vol. 270, Oct. 20, 1995):

Definitions

- "Genetic information" is information about genes, gene products, or inherited characteristics that may derive from the individual or a family member.

- "Insurance provider" means an insurance company, employer, or any other entity providing a plan of health insurance or health benefits, including group and individual health plans whether fully insured or self-funded.

Recommendations
• Insurance providers should be prohibited from using genetic information or an individual's request for genetic services to deny or limit any coverage or establish eligibility, continuation, enrollment, or contribution requirements.

• Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services.

• Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information. Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without the individual's prior written authorization. Written authorization should be required for each disclosure and include to whom the disclosure would be made.

A final report of the ELSI Working Group was released in 1996.

V. Why Legislation Was Needed

(1) Based on genetic information, employers may try to avoid hiring workers they believe are likely to take sick leave, resign, or retire early for health reasons (creating extra costs in recruiting and training new staff), file for workers' compensation, or use healthcare benefits excessively.

(2) Some employers may seek to use genetic tests to discriminate against workers—even those who do not and may never show signs of disease—because the employers fear the cost consequences.

(3) The economic incentive to discriminate based on genetic information is likely to increase as genetic research advances and the costs of genetic testing decrease.

(4) Genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy and unlikely to develop disease or where the genetic condition has no effect on the ability to perform work.

(5) Given the substantial gaps in state and federal protections against employment discrimination based on genetic information, comprehensive federal legislation is needed to ensure that advances in genetic technology and research are used to address the health needs of the nation—and not to deny individuals employment opportunities and benefits. Federal legislation would establish minimum protections that...
could be supplemented by state laws.

(6) Insurers can still use genetic information in the individual market in decisions about coverage, enrollment, and premiums.

(7) Insurers can still require individuals to take genetic tests.

(8) Individuals are not protected from the disclosure of genetic information to insurers, plan sponsors (employers), and medical information bureaus, without their consent.

(9) Penalties in HIPAA for discrimination and disclosure violations should be strengthened in order to ensure individuals of the protections afforded by the legislation.

VI. Landmark Cases of Genetic Discrimination

Although no genetic-employment discrimination case has been brought before U.S. federal or state courts, in 2001 the Equal Employment Opportunity Commission (EEOC) settled the first lawsuit alleging this type of discrimination.

EEOC filed a suit against the Burlington Northern Santa Fe (BNSF) Railroad for secretly testing its employees for a rare genetic condition that causes carpal tunnel syndrome as one of its many symptoms. BNSF claimed that the testing was a way of determining whether the high incidence of repetitive-stress injuries among its employees was work-related. Besides testing for this rare problem, company-paid doctors also were instructed to screen for several other medical conditions such as diabetes and alcoholism. BNSF employees examined by company doctors were not told that they were being genetically tested. One employee who refused testing was threatened with possible termination.

On behalf of BNSF employees, EEOC argued that the tests were unlawful under the Americans with Disabilities Act because they were not job-related, and any condition of employment based on such tests would be cause for illegal discrimination based on disability. The lawsuit was settled quickly with BNSF agreeing to everything sought by EEOC.

Besides the BNSF case, the Council for Responsible Genetics claims that hundreds of genetic-discrimination cases have been documented and describes select cases in its Genetic Discrimination Position Paper (PDF). In one case, genetic testing indicated that a young boy had Fragile X Syndrome, an inherited form of mental retardation. The insurance company for the boy's family dropped his health coverage,
claiming the syndrome was a preexisting condition. In another case, a social worker lost her job within a week of mentioning that her mother had died of Huntington's disease and that she had a 50% chance of developing it.

Despite claims of hundreds of genetic-discrimination incidents, an article from the January 2003 issue of the *European Journal of Human Genetics* reports a real need for a comprehensive investigation of these claims. The article warns that many studies rely on unverified, subjective accounts from individuals who believe they have been unfairly subjected to genetic discrimination by employers or insurance companies. Rarely are these subjective accounts assessed objectively to determine whether actions taken by employers and insurers were truly based on genetic factors or other legitimate concerns.

### VII. More Information

#### Web Sites

- [Policy & Ethics Current Topics: Privacy, Discrimination and Legal Issues](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml) - Links to policy and legislative information on genetic privacy, genetic discrimination, patenting genetic information, and DNA forensics. From the National Human Genome Research Institute.
- [Genetic Education Materials (GEM) Database](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml) - Searchable listing of public health genetics policy documents and clinical genetics educational materials. From the National Newborn Screening and Genetics Resource Center (NNSGRC).
- [Workplace Rights: Genetic Discrimination](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml) - Information from the American Civil Liberties Union.

#### Organizations

- [Genetics & Public Policy Center](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml)
- [Council for Responsible Genetics](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml)
- [National Patient Advocate Foundation](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml)
- [American Civil Liberties Union](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml)
- [Health Privacy Project](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml)
- [Privacy Rights Clearinghouse](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml)

#### Position Statements


- American College of Medical Genetics (PDF) - Points to Consider in Preventing Unfair Discrimination Based on Genetic Disease Risk, December 2001.

Articles

- New Federal Privacy Rules Stump Researchers - The Scientist 15: 33, September 17, 2001 - A new federal privacy rule in the Health Insurance Portability and Accountability Act of 1996 (HIPAA)--requires researchers who use the nation's tissue banks to obtain authorizations when they use patient-specific information, such as medical histories. As of April 2003, both criminal and civil penalties for violations can be applied.
- Pink Slip in Your Genes - Scientific American, January 2001 - Evidence builds that employers hire and fire based on genetic tests; meanwhile, protective legislation languishes.
- Does Genetic Research Threaten Our Civil Liberties? - Article from actionbioscience.org, August 2000. Mapping the human genome may lead to new medical breakthroughs; however, it may also lead to an individual's loss of privacy, discrimination by class or genetic profile, and genetic enhancement of select individuals or populations.

Books


Information on this page was taken from several sources, including the NIH NHGRI Legislation Office in the Office of Policy Coordination, Department of Labor, Human Genome News, National Action Plan on Breast Cancer, and U.S. Department of Energy–
National Institutes of Health Working Group on Ethical, Legal, and Social Implications of Genome Research.

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Public Law 110–233
110th Congress

An Act
To prohibit discrimination on the basis of genetic information with respect to health insurance and employment.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Genetic Information Nondiscrimination Act of 2008”.

(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. 102. Amendments to the Public Health Service Act.
Sec. 103. Amendments to the Internal Revenue Code of 1986.
Sec. 104. Amendments to title XVIII of the Social Security Act relating to medigap.
Sec. 105. Privacy and confidentiality.
Sec. 106. Assuring coordination.

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

Sec. 201. Definitions.
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 PROVISIONS

Sec. 301. Severability.
Sec. 302. Child labor protections.

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) 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—

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

(2) by adding at the end the following:

“(3) NO GROUP-BASED DISCRIMINATION ON BASIS OF GENETIC INFORMATION.—

“(A) IN GENERAL.—For purposes of this section, a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information.

“(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) or in paragraphs (1) and (2) of subsection (d) shall be construed to limit the ability of a health insurance issuer offering health insurance coverage in connection with a group health plan to increase the premium for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer.”.

(b) LIMITATIONS ON GENETIC TESTING; PROHIBITION ON COLLECTION OF GENETIC INFORMATION; APPLICATION TO ALL PLANS.—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, and 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.—Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

“(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—

“(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to preclude a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the
Secretary of Health and Human Services under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a).

"(B) LIMITATION.—For purposes of subparagraph (A), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request only the minimum amount of information necessary to accomplish the intended purpose.

"(4) RESEARCH EXCEPTION.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

"(A) The request is made, in writing, pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

"(B) The plan or issuer clearly indicates to each participant or beneficiary, or in the case of a minor child, to the legal guardian of such beneficiary, to whom the request is made that—

"(i) compliance with the request is voluntary; and

"(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

"(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

"(D) The plan or issuer notifies the Secretary in writing that the plan or issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

"(E) The plan or issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

"(d) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

"(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 733).

"(2) PROHIBITION ON COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the plan or coverage in connection with such enrollment.

"(3) INCIDENTAL COLLECTION.—If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation Notification.
of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

(e) APPLI CATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), (c), and (d), and subsection (b)(1) and section 701 with respect to genetic information, shall apply to group health plans and health insurance issuers without regard to section 732(a)."

(c) APPLI CATION TO GENETIC INFORMATION OF A FETUS OR EMBRYO.—Such section is further amended by adding at the end the following:

“(f) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this part to genetic information concerning an individual or family member of an individual shall—

“(1) 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; and

“(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.”

(d) 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) a dependent (as such term is used for purposes of section 701(f)(2)) of such individual, and

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

“(6) GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘genetic information’ means, with respect to any individual, information about—

“(i) such individual’s genetic tests,

“(ii) the genetic tests of family members of such individual, and

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

“(B) INCLUSION OF GENETIC SERVICES AND PARTICIPATION IN GENETIC RESEARCH.—Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

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

“(9) Underwriting purposes.—The term ‘underwriting purposes’ means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—
“(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;
“(B) the computation of premium or contribution amounts under the plan or coverage;
“(C) the application of any pre-existing condition exclusion under the plan or coverage; and
“(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.”.

(e) 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)”;
“(2) in subsection (b)(3), by striking “The Secretary” and inserting “Except as provided in subsections (c)(9) and (a)(6) (with respect to collecting civil penalties under subsection (c)(9)), the Secretary”;
“(3) 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), (c), or (d) of section 702 or section 701 or 702(b)(1) with respect to genetic information, 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 the 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.”.

(f) REGULATIONS AND EFFECTIVE DATE.—

(1) REGULATIONS.—The Secretary of Labor shall issue final regulations not later than 12 months 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 1 year after the date of enactment of this Act.

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

(a) AMENDMENTS RELATING TO THE GROUP MARKET.—

(1) 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—

(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 GROUP-BASED DISCRIMINATION ON BASIS OF GENETIC INFORMATION.—

“(A) IN GENERAL.—For purposes of this section, a group health plan, and health insurance issuer offering group health insurance coverage in connection with a group health plan, may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information.

“(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) or in paragraphs (1) and (2) of subsection (d) shall be construed to limit the ability of a health insurance issuer offering health insurance coverage in connection with a group health plan to increase the premium for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer.”.

(2) LIMITATIONS ON GENETIC TESTING; PROHIBITION ON COLLECTION OF GENETIC INFORMATION; APPLICATION TO ALL PLANS.—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, and 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.—Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

“(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—
“(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to preclude a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a).

“(B) LIMITATION.—For purposes of subparagraph (A), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request only the minimum amount of information necessary to accomplish the intended purpose.

“(4) RESEARCH EXCEPTION.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

“(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

“(B) The plan or issuer clearly indicates to each participant or beneficiary, or in the case of a minor child, to the legal guardian of such beneficiary, to whom the request is made that—

“(i) compliance with the request is voluntary; and

“(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

“(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

“(D) The plan or issuer notifies the Secretary in writing that the plan or issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

“(E) The plan or issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

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

“(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 2791).

“(2) PROHIBITION ON COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information with respect to any individual prior to such individual’s enrollment under the plan or coverage in connection with such enrollment.
“(3) INCIDENTAL COLLECTION.—If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

“(e) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), (c), and (d) and subsection (b)(1) and section 2701 with respect to genetic information, shall apply to group health plans and health insurance issuers without regard to section 2721(a).”.

“(3) APPLICATION TO GENETIC INFORMATION OF A FETUS OR EMBRYO.—Such section is further amended by adding at the end the following:

“(f) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this part to genetic information concerning an individual or family member of an individual shall—

“(1) 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; and

“(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.”.

“(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 any individual—

“(A) a dependent (as such term is used for purposes of section 2701(f)(2)) of such individual; and

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

“(16) GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘genetic information’ means, with respect to any individual, information about—

“(i) such individual’s genetic tests,

“(ii) the genetic tests of family members of such individual, and

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

“(B) INCLUSION OF GENETIC SERVICES AND PARTICIPATION IN GENETIC RESEARCH.—Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

“(C) EXCLUSIONS.—The term ‘genetic information’ shall not include information about the sex or age of any 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 (including obtaining, interpreting, or assessing genetic information); or

"(C) genetic education.

"(19) UNDERWRITING PURPOSES.—The term ‘underwriting purposes’ means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

"(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;

"(B) the computation of premium or contribution amounts under the plan or coverage;

"(C) the application of any pre-existing condition exclusion under the plan or coverage; and

"(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.”.

(5) 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 succeeding subparagraphs of this paragraph 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), (c), or (d) of section 2702 or section 2701 or 2702(b)(1) with respect to genetic information in connection with the plan.

"(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 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 the 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.”.

(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.—

(1) IN GENERAL.—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.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from establishing rules for eligibility for an individual to enroll in individual health insurance coverage based on the manifestation of a disease or disorder in that individual, or in a family member of such individual where such family member is covered under the policy that covers such individual.

(b) PROHIBITION ON GENETIC INFORMATION IN SETTING PREMIUM RATES.—

(1) IN GENERAL.—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.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from adjusting premium or contribution amounts for an individual on the basis of a manifestation of a disease or disorder in that individual, or in a family member of such individual where such family member is covered under the policy that covers such individual. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals covered under the policy issued to such individual and to further increase premiums or contribution amounts.

(c) PROHIBITION ON GENETIC INFORMATION AS PREEXISTING CONDITION.—

(1) IN GENERAL.—A health insurance issuer offering health insurance coverage in the individual market may not, on the basis of genetic information, impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A)) with respect to such coverage.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from imposing any preexisting condition exclusion for an individual with respect to health insurance coverage on the basis of a manifestation of a disease or disorder in that individual.

(d) 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.—Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

“(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—

“(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to preclude a health insurance issuer offering health insurance coverage in the individual market from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a) and (c).

“(B) LIMITATION.—For purposes of subparagraph (A), a health insurance issuer offering health insurance coverage in the individual market may request only the minimum amount of information necessary to accomplish the intended purpose.

“(4) RESEARCH EXCEPTION.—Notwithstanding paragraph (1), a health insurance issuer offering health insurance coverage in the individual market may request, but not require, that an individual or a family member of such individual undergo a genetic test if each of the following conditions is met:

“(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

“(B) The issuer clearly indicates to each individual, or in the case of a minor child, to the legal guardian of such child, to whom the request is made that—

“(i) compliance with the request is voluntary; and

“(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

“(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

“(D) The issuer notifies the Secretary in writing that the issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

“(E) The issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

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

“(1) IN GENERAL.—A health insurance issuer offering health insurance coverage in the individual market shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 2791).

“(2) PROHIBITION ON COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A health insurance issuer offering
health insurance coverage in the individual market shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the plan in connection with such enrollment.

(3) INCIDENTAL COLLECTION.—If a health insurance issuer offering health insurance coverage in the individual market obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

“(f) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this part to genetic information concerning an individual or family member of an individual shall—

“(1) 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; and

“(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.”.

(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”;

(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), (b)(3), (c), and (d) of section 2702 and the provisions of sections 2701 and 2702(b) to the extent that such provisions apply to genetic information.”.

(d) REGULATIONS AND EFFECTIVE DATE.—

(1) REGULATIONS.—Not later than 12 months after the date of enactment of this Act, 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—

42 USC 300gg–1 note.
(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 1 year after the date of enactment of this Act; 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 1 year after the date of enactment of this Act.

SEC. 103. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

(a) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMATION.—Subsection (b) of section 9802 of the Internal Revenue Code of 1986 is amended—

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

(2) by adding at the end the following:

“(3) NO GROUP-BASED DISCRIMINATION ON BASIS OF GENETIC INFORMATION.—

“(A) IN GENERAL.—For purposes of this section, a group health plan may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information.

“(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) or in paragraphs (1) and (2) of subsection (d) shall be construed to limit the ability of a group health plan to increase the premium for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer.”.

(b) LIMITATIONS ON GENETIC TESTING; PROHIBITION ON COLLECTION OF GENETIC INFORMATION; APPLICATION TO ALL PLANS.—Section 9802 of such Code is amended by redesignating subsection (c) as subsection (f) and by inserting after subsection (b) the following new subsections:

“(c) GENETIC TESTING.—

“(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan may not request or require an individual or a family member of such individual to undergo a genetic test.

“(2) RULE OF CONSTRUCTION.—Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

“(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—

“(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to preclude a group health plan from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a).
“(B) LIMITATION.—For purposes of subparagraph (A), a group health plan may request only the minimum amount of information necessary to accomplish the intended purpose.

“(4) RESEARCH EXCEPTION.—Notwithstanding paragraph (1), a group health plan may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

“(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

“(B) The plan clearly indicates to each participant or beneficiary, or in the case of a minor child, to the legal guardian of such beneficiary, to whom the request is made that—

“(i) compliance with the request is voluntary; and

“(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

“(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

“(D) The plan notifies the Secretary in writing that the plan is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

“(E) The plan complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

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

“(1) IN GENERAL.—A group health plan shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 9832).

“(2) PROHIBITION ON COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan shall not request, require, or purchase genetic information with respect to any individual prior to such individual’s enrollment under the plan or in connection with such enrollment.

“(3) INCIDENTAL COLLECTION.—If a group health plan obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

“(e) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), (c), and (d) and subsection (b)(1) and section 9801 with respect to genetic information, shall apply to group health plans without regard to section 9831(a)(2).”.

“(c) APPLICATION TO GENETIC INFORMATION OF A FETUS OR EMBRYO.—Such section is further amended by adding at the end the following:

“(f) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this chapter to genetic information concerning an individual or family member of an individual shall—

“(1) 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; and

“(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.”.

26 USC 9832.

(d) DEFINITIONS.—Subsection (d) of section 9832 of such Code is amended by adding at the end the following:

“(6) FAMILY MEMBER.—The term ‘family member’ means, with respect to any individual—

“(A) a dependent (as such term is used for purposes of section 9801(f)(2)) of such individual, and

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

“(7) GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘genetic information’ means, with respect to any individual, information about—

“(i) such individual’s genetic tests,

“(ii) the genetic tests of family members of such individual, and

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

“(B) INCLUSION OF GENETIC SERVICES AND PARTICIPATION IN GENETIC RESEARCH.—Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

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

“(8) 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.

“(9) 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.

“(10) UNDERWRITING PURPOSES.—The term ‘underwriting purposes’ means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—
“(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;
“(B) the computation of premium or contribution amounts under the plan or coverage;
“(C) the application of any pre-existing condition exclusion under the plan or coverage; and
“(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.”.

(e) ENFORCEMENT.—
  (1) IN GENERAL.—Subchapter C of chapter 100 of the Internal Revenue Code of 1986 (relating to general provisions) is amended by adding at the end the following new section:

“SEC. 9834. ENFORCEMENT.
  “For the imposition of tax on any failure of a group health plan to meet the requirements of this chapter, see section 4980D.”.

  (2) CONFORMING AMENDMENT.—The table of sections for subchapter C of chapter 100 of such Code is amended by adding at the end the following new item:

“Sec. 9834. Enforcement.”.

(f) REGULATIONS AND EFFECTIVE DATE.—
  (1) REGULATIONS.—The Secretary of the Treasury shall issue final regulations or other guidance not later than 12 months after the date of the 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 1 year after the date of the enactment of this Act.

SEC. 104. AMENDMENTS TO TITLE XVIII OF THE SOCIAL SECURITY ACT RELATING TO MEDIGAP.

(a) NONDISCRIMINATION.—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) An issuer of a medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy (including the imposition of any exclusion of benefits under the policy based on a pre-existing condition) and shall not discriminate in the pricing of the policy (including the adjustment of premium rates) of an individual on the basis of the genetic information with respect to such individual.

“(F) RULE OF CONSTRUCTION.—Nothing in subparagraph (E) or in subparagraphs (A) or (B) of subsection (x)(2) shall be construed to limit the ability of an issuer of a medicare supplemental policy from, to the extent otherwise permitted under this title—

  “(i) denying or conditioning the issuance or effectiveness of the policy or increasing the premium for an employer based on the manifestation of a disease or disorder of an individual who is covered under the policy; or

  “(ii) increasing the premium for any policy issued to an individual based on the manifestation of a disease
or disorder of an individual who is covered under the policy (in such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer).”.

(b) **Limitations on Genetic Testing and Genetic Information.**

(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 and Information.**—

“(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.**—Subparagraph (A) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

“(C) **Rule of Construction Regarding Payment.**—

“(i) **In General.**—Nothing in subparagraph (A) shall be construed to preclude an issuer of a medicare supplemental policy from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (s)(2)(E).

“(ii) **Limitation.**—For purposes of clause (i), an issuer of a medicare supplemental policy may request only the minimum amount of information necessary to accomplish the intended purpose.

“(D) **Research Exception.**—Notwithstanding subparagraph (A), an issuer of a medicare supplemental policy may request, but not require, that an individual or a family member of such individual undergo a genetic test if each of the following conditions is met:

“(i) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

“(ii) The issuer clearly indicates to each individual, or in the case of a minor child, to the legal guardian of such child, to whom the request is made that—

“(I) compliance with the request is voluntary; and

“(II) non-compliance will have no effect on enrollment status or premium or contribution amounts.
“(iii) No genetic information collected or acquired under this subparagraph shall be used for underwriting, determination of eligibility to enroll or maintain enrollment status, premium rating, or the creation, renewal, or replacement of a plan, contract, or coverage for health insurance or health benefits.

“(iv) The issuer notifies the Secretary in writing that the issuer is conducting activities pursuant to the exception provided for under this subparagraph, including a description of the activities conducted.

“(v) The issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this subparagraph.

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

“(A) IN GENERAL.—An issuer of a medicare supplemental policy shall not request, require, or purchase genetic information for underwriting purposes (as defined in paragraph (3)).

“(B) PROHIBITION ON COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—An issuer of a medicare supplemental policy shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the policy in connection with such enrollment.

“(C) INCIDENTAL COLLECTION.—If an issuer of a medicare supplemental policy obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of subparagraph (B) if such request, requirement, or purchase is not in violation of subparagraph (A).

“(3) DEFINITIONS.—In this subsection:

“(A) FAMILY MEMBER.—The term ‘family member’ means with respect to an individual, any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual.

“(B) GENETIC INFORMATION.—

“(i) IN GENERAL.—The term ‘genetic information’ means, with respect to any individual, information about—

“(I) such individual’s genetic tests,

“(II) the genetic tests of family members of such individual, and

“(III) subject to clause (iv), the manifestation of a disease or disorder in family members of such individual.

“(ii) INCLUSION OF GENETIC SERVICES AND PARTICIPATION IN GENETIC RESEARCH.—Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

“(iii) EXCLUSIONS.—The term ‘genetic information’ shall not include information about the sex or age of any 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 (including obtaining, interpreting, or assessing genetic information); or

“(iii) genetic education.

“(E) UNDERWRITING PURPOSES.—The term ‘underwriting purposes’ means, with respect to a medicare supplemental policy—

“(i) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the policy;

“(ii) the computation of premium or contribution amounts under the policy;

“(iii) the application of any pre-existing condition exclusion under the policy; and

“(iv) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

“(F) 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) APPLICATION TO GENETIC INFORMATION OF A FETUS OR EMBRYO.—Section 1882(x) of such Act, as added by paragraph (1), is further amended by adding at the end the following:

“(4) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this section to genetic information concerning an individual or family member of an individual shall—

“(A) 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; and

“(B) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.”.

(3) 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).”.
(c) **EFFECTIVE DATE.**—The amendments made by this section shall apply with respect to an issuer of a medicare supplemental policy for policy years beginning on or after the date that is 1 year after the date of enactment of this Act.

(d) **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 regulatory program to the changes made by this section, the State regulatory program 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 October 31, 2008, the National Association of Insurance Commissioners (in this subsection referred to as the "NAIC") modifies its NAIC Model Regulation relating to section 1882 of the Social Security Act (referred to in such section as the 1991 NAIC Model Regulation, as subsequently 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 described in paragraph (2) within the period specified in such paragraph, the Secretary of Health and Human Services shall, not later than July 1, 2009, make the modifications described in such paragraph and such revised regulation 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) July 1, 2009.

(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 2009 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, 2009. 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. 105. PRIVACY AND CONFIDENTIALITY.**

(a) **IN GENERAL.**—Part C of title XI of the Social Security Act is amended by adding at the end the following new section:
APPLICATION OF HIPAA REGULATIONS TO GENETIC INFORMATION

42 USC 1320d–9.

"SEC. 1180. (a) In General.—The Secretary shall revise the HIPAA privacy regulation (as defined in subsection (b)) so it is consistent with the following:

“(1) Genetic information shall be treated as health information described in section 1171(4)(B).

“(2) The use or disclosure by a covered entity that is a group health plan, health insurance issuer that issues health insurance coverage, or issuer of a medicare supplemental policy of protected health information that is genetic information about an individual for underwriting purposes under the group health plan, health insurance coverage, or medicare supplemental policy shall not be a permitted use or disclosure.

“(b) Definitions.—For purposes of this section:

“(1) Genetic information; genetic test; family member.—The terms 'genetic information', 'genetic test', and 'family member' have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), as amended by the Genetic Information Nondiscrimination Act of 2007.

“(2) Group health plan; health insurance coverage; medicare supplemental policy.—The terms 'group health plan' and 'health insurance coverage' have the meanings given such terms under section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), and the term 'medicare supplemental policy' has the meaning given such term in section 1882(g).

“(3) HIPAA privacy regulation.—The term 'HIPAA privacy regulation' means the regulations promulgated by the Secretary under this part and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

“(4) Underwriting purposes.—The term 'underwriting purposes' means, with respect to a group health plan, health insurance coverage, or a medicare supplemental policy—

“(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy;

“(B) the computation of premium or contribution amounts under the plan, coverage, or policy;

“(C) the application of any pre-existing condition exclusion under the plan, coverage, or policy; and

“(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

“(c) Procedure.—The revisions under subsection (a) shall be made by notice in the Federal Register published not later than 60 days after the date of the enactment of this section and shall be effective upon publication, without opportunity for any prior public comment, but may be revised, consistent with this section, after opportunity for public comment.

“(d) Enforcement.—In addition to any other sanctions or remedies that may be available under law, a covered entity that is a group health plan, health insurance issuer, or issuer of a medicare supplemental policy and that violates the HIPAA privacy regulation (as revised under subsection (a) or otherwise) with respect to the use or disclosure of genetic information shall be subject to the
penalties described in sections 1176 and 1177 in the same manner and to the same extent that such penalties apply to violations of this part.

(b) Regulations; Effective Date.

(1) Regulations.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue final regulations to carry out the revision required by section 1180(a) of the Social Security Act, as added by subsection (a). The Secretary has the sole authority to promulgate such regulations, but shall promulgate such regulations in consultation with the Secretaries of Labor and the Treasury.

(2) Effective Date.—The amendment made by subsection (a) shall take effect on the date that is 1 year after the date of the enactment of this Act.

SEC. 106. ASSURING COORDINATION.

Except as provided in section 105(b)(1), the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall ensure, through the execution of an inter-agency 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 responsibility 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.

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

SEC. 201. DEFINITIONS.

In this title:


(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) a dependent (as such term is used for purposes of section 701(f)(2) of the Employee Retirement Income Security Act of 1974) of such individual, and
(B) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual or of an individual described in subparagraph (A).

(4) GENETIC INFORMATION.—
(A) IN GENERAL.—The term “genetic information” means, with respect to any individual, information about—
(i) such individual's genetic tests,
(ii) the genetic tests of family members of such individual, and
(iii) the manifestation of a disease or disorder in family members of such individual.
(B) INCLUSION OF GENETIC SERVICES AND PARTICIPATION IN GENETIC RESEARCH.—Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

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

(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 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 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) or 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;

(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; or

(6) where the employer conducts DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification, and requests or requires genetic information of such employer’s employees, but only to the extent that such genetic information is used for analysis of DNA identification markers for quality control to detect sample contamination.

(c) PRESERVATION OF PROTECTIONS.—In the case of information to which any of paragraphs (1) through (6) 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.
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

(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 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 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.
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;

(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

(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 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 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), (2), or (3) 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 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

(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 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 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;

(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; or
(6) where the employer conducts DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification, and requests or requires genetic information of such employer’s apprentices or trainees, but only to the extent that such genetic information is used for analysis of DNA identification markers for quality control to detect sample contamination.
(c) PRESERVATION OF PROTECTIONS.—In the case of information to which any of paragraphs (1) through (6) of subsection (b) applies, such information may not be used in violation of paragraph (1), (2), or (3) 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, 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 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; 
(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; or 
(6) to a Federal, State, or local public health agency only with regard to information that is described in section 201(4)(A)(iii) and that concerns a contagious disease that presents an imminent hazard of death or life-threatening illness, and that the employee whose family member or family members is or are the subject of a disclosure under this paragraph is notified of such disclosure.

(c) RELATIONSHIP TO HIPAA REGULATIONS.—With respect to 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), this title does not prohibit a covered entity under such regulations from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

SEC. 207. REMEDIES AND ENFORCEMENT.

(a) EMPLOYEES COVERED BY TITLE VII OF THE CIVIL RIGHTS ACT OF 1964.—
   (1) IN GENERAL.—The powers, procedures, and remedies 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.) shall be the powers, procedures, and remedies this title provides 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, procedures, and remedies 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–16(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) PROHIBITION AGAINST RETALIATION.—No person shall discriminate against any individual because such individual has opposed any act or practice made unlawful by this title or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this title. The remedies and procedures otherwise provided for under this section shall be available to aggrieved individuals with respect to violations of this subsection.

(g) 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 Nondiscrimination 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


Effective date. Establishment.
(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 subject to enforcement for a violation under—

(i) the amendments made by title I of this Act;

(ii)(I) subsection (a) of section 701 of the Employee Retirement Income Security Act of 1974 as such section applies with respect to genetic information pursuant to subsection (b)(1)(B) of such section;

(II) section 702(a)(1)(F) of such Act; or

(III) section 702(b)(1) of such Act as such section applies with respect to genetic information as a health status-related factor;

(iii)(I) subsection (a) of section 2701 of the Public Health Service Act as such section applies with respect to genetic information pursuant to subsection (b)(1)(B) of such section;

(II) section 2702(a)(1)(F) of such Act; or

(III) section 2702(b)(1) of such Act as such section applies with respect to genetic information as a health status-related factor; or

(iv)(I) subsection (a) of section 9801 of the Internal Revenue Code of 1986 as such section applies with respect to genetic information pursuant to subsection (b)(1)(B) of such section;

(II) section 9802(a)(1)(F) of such Act; or

(III) section 9802(b)(1) of such Act as such section applies with respect to genetic information as a health status-related factor;

(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.

Applicability.

(b) Genetic Information of a Fetus or Embryo.—Any reference in this title to genetic information concerning an individual or family member of an individual shall—

(1) 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; and
(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

(c) Relation to Authorities Under Title I.—With respect to a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, this title does not prohibit any activity of such plan or issuer that is authorized for the plan or issuer under any provision of law referred to in clauses (i) through (iv) of subsection (a)(2)(B).

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 PROVISIONS

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.

SEC. 302. CHILD LABOR PROTECTIONS.

(a) In General.—Section 16(e) of the Fair Labor Standards Act of 1938 (29 U.S.C. 216(e)) is amended to read as follows:

"(e)(1)(A) Any person who violates the provisions of sections 12 or 13(c), relating to child labor, or any regulation issued pursuant to such sections, shall be subject to a civil penalty not to exceed—

"(i) $11,000 for each employee who was the subject of such a violation; or

"(ii) $50,000 with regard to each such violation that causes the death or serious injury of any employee under the age of 18 years, which penalty may be doubled where the violation is a repeated or willful violation."
“(B) For purposes of subparagraph (A), the term ‘serious injury’ means—

“(i) permanent loss or substantial impairment of one of the senses (sight, hearing, taste, smell, tactile sensation);
“(ii) permanent loss or substantial impairment of the function of a bodily member, organ, or mental faculty, including the loss of all or part of an arm, leg, foot, hand or other body part; or
“(iii) permanent paralysis or substantial impairment that causes loss of movement or mobility of an arm, leg, foot, hand or other body part.

“(2) Any person who repeatedly or willfully violates section 6 or 7, relating to wages, shall be subject to a civil penalty not to exceed $1,100 for each such violation.

“(3) In determining the amount of any penalty under this subsection, the appropriateness of such penalty to the size of the business of the person charged and the gravity of the violation shall be considered. The amount of any penalty under this subsection, when finally determined, may be—

“(A) deducted from any sums owing by the United States to the person charged;
“(B) recovered in a civil action brought by the Secretary in any court of competent jurisdiction, in which litigation the Secretary shall be represented by the Solicitor of Labor; or
“(C) ordered by the court, in an action brought for a violation of section 15(a)(4) or a repeated or willful violation of section 15(a)(2), to be paid to the Secretary.

“(4) Any administrative determination by the Secretary of the amount of any penalty under this subsection shall be final, unless within 15 days after receipt of notice thereof by certified mail the person charged with the violation takes exception to the determination that the violations for which the penalty is imposed occurred, in which event final determination of the penalty shall be made in an administrative proceeding after opportunity for hearing in accordance with section 554 of title 5, United States Code, and regulations to be promulgated by the Secretary.

“(5) Except for civil penalties collected for violations of section 12, sums collected as penalties pursuant to this section shall be applied toward reimbursement of the costs of determining the violations and assessing and collecting such penalties, in accordance with the provision of section 2 of the Act entitled ‘An Act to authorize the Department of Labor to make special statistical studies upon payment of the cost thereof and for other purposes’ (29 U.S.C. 9a). Civil penalties collected for violations of section 12 shall be deposited in the general fund of the Treasury.”.
(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act.

Approved May 21, 2008.
The information presented in this fact sheet is intended for general informational purposes only. While this fact sheet does not cover all of the specifics of GINA, it does provide an explanation of the statute to assist those involved in clinical research to understand the law and its prohibitions related to discrimination in health coverage and employment based on genetic information. The information should not be considered legal advice. In addition, some of the provisions discussed involve issues for which the rules have not yet been finalized, and this information is subject to revision based on publication of regulations.

What is GINA?
The Genetic Information Nondiscrimination Act of 2008 (P.L. 110-233, 122 Stat. 881)¹, also referred to as GINA, is a new Federal law that prohibits discrimination in health coverage and employment based on genetic information. The President signed the act into law on May 21, 2008. The section of the law relating to health coverage (Title I) generally will take effect between May 22, 2009, and May 21, 2010.² The sections relating to employment (Title II) will take effect on November 21, 2009. GINA requires regulations pertaining to both titles to be completed by May 2009.

How does the Federal law affect state laws?
GINA provides a baseline level of protection against genetic discrimination for all Americans. Many states already have laws that protect against genetic discrimination in health insurance and employment situations. However, the degree of protection they provide varies widely, and while most provisions are less protective than GINA, some are more protective. All entities that are subject to GINA must, at a minimum, comply with all applicable GINA requirements, and may also need to comply with more protective State laws.


² The effective date of the insurance provisions is not the same in all cases because for group health plans, Title I will take effect at the start of the “plan year” beginning one year after GINA’s enactment. Because some health plans do not designate their “plan years” to correspond to a calendar year, there will be variation among plans as to when Title I takes effect for the plans. However, for individual health insurers, GINA will take effect May 22, 2009.
What will GINA do?
GINA generally will prohibit discrimination in health coverage and employment on the basis of genetic information. GINA, together with already existing nondiscrimination provisions of the Health Insurance Portability and Accountability Act, generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual’s family members, or using it for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment.

The statute defines ‘genetic information’ as information about:
- an individual’s genetic tests (including genetic tests done as part of a research study);
- genetic tests of the individual’s family members (defined as dependents and up to and including 4th degree relatives);
- genetic tests of any fetus of an individual or family member who is a pregnant woman, and genetic tests of any embryo legally held by an individual or family member utilizing assisted reproductive technology;
- the manifestation of a disease or disorder in family members (family history);
- any request for, or receipt of, genetic services or participation in clinical research that includes genetic services (genetic testing, counseling, or education) by an individual or family member.

Genetic information does not include information about the sex or age of any individual.

The statute defines ‘genetic test’ as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. The results of routine tests that do not measure DNA, RNA, or chromosomal changes, such as complete blood counts, cholesterol tests, and liver-function tests, are not protected under GINA. Also, under GINA, genetic tests do not include analyses of proteins or metabolites that are 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.

How will the law be enforced and what are the penalties for violation of the law?
The law will be enforced by various Federal agencies. The Department of Labor, the Department of the Treasury, and the Department of Health and Human Services are responsible for Title I of GINA, and the Equal Employment Opportunity Commission (EEOC) is responsible for Title II of GINA. Remedies for violations include corrective action and monetary penalties. Under Title II of GINA, individuals may also have the right to pursue private litigation.

What won’t GINA do?
- GINA’s health coverage non-discrimination protections do not extend to life insurance, disability insurance and long-term care insurance.
- GINA does not mandate coverage for any particular test or treatment.
GINA’s employment provisions generally do not apply to employers with fewer than 15 employees.

For health coverage provided by a health insurer to individuals, GINA does not prohibit the health insurer from determining eligibility or premium rates for an individual based on the manifestation of a disease or disorder in that individual. For employment-based coverage provided by group health plans, GINA permits the overall premium rate for an employer to be increased because of the manifestation of a disease or disorder in an individual enrolled in the plan, but the manifested disease or disorder of one individual cannot be used as genetic information about other group members to further increase the premium.

GINA does not prohibit health insurers or health plan administrators from obtaining and using genetic test results in making health insurance payment determinations.

What is the status of regulations to implement GINA?
The law requires regulations by May 2009. The Department of Health and Human Services (Centers for Medicare & Medicaid Services (CMS) and the Office for Civil Rights), the Department of Labor, the Department of the Treasury (the Internal Revenue Service), and the EEOC are currently working on the regulations. The Department of Labor, the Department of the Treasury, and CMS put forth a Request for Information about issues relevant to some of the health coverage provisions in Title I on October 10, 2008, which closed on December 9, 2008.3

Is GINA retroactive?
GINA will not be retroactive, i.e., it cannot apply to acts or omissions that occurred prior to GINA’s effective dates. However, once GINA takes effect, it will prohibit certain uses of genetic information in connection with health coverage and employment, no matter when the information was collected. For example, a health insurer that has been collecting or using genetic information for underwriting would need to change its business practices once GINA takes effect. Likewise, certain employers requiring genetic tests or family history information from employees or prospective employees will no longer be able to do so after GINA takes effect and will be prohibited from discriminating based on any genetic information that they had already collected.

Does GINA have specific research provisions?
Yes. GINA’s prohibitions apply to “genetic information” which is defined as including receipt of genetic services (genetic tests, genetic counseling, or genetic education) by an individual or family member participating in clinical research. There is, however, a research exception.

GINA provides a specific “research exception” to allow health insurers or group health plans engaged in research to request (but not require) that an individual undergo a genetic

test. This exception permits the request to be made but imposes the following requirements:

(1) the request must be made pursuant to research that complies with HHS regulations at 45 CFR part 46, or equivalent Federal regulations, and any applicable state or local laws for the protection of human subjects in research;
(2) there must be clear indication that participation is voluntary and that non-compliance has no effect on enrollment or premiums or contribution amounts;
(3) no genetic information collected or acquired as part of the research may be used for underwriting purposes;
(4) the health insurer or group health plan must notify the Federal government in writing that it is conducting activities pursuant to this research exception and provide a description of the activities conducted; and
(5) the health insurer or group health plan must comply with any future conditions that the Federal government may require for activities conducted under this research exception.

What information about GINA should be communicated as part of the informed consent process to individuals participating in a research study or those considering study participation?
Although GINA has not yet taken effect, there may currently be situations where it is appropriate for researchers to discuss the provisions of the law with individuals participating in a research study or those considering study participation. For more information, see the following guidance document prepared by the Office for Human Research Protections: http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html (URL), http://www.hhs.gov/ohrp/humansubjects/guidance/gina.pdf (PDF).