

The New Genetic Information Nondiscrimination Act- How It Came to Pass and What It Does

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Just last year, the Genetic Information Nondiscrimination Act (GINA), hailed by Senator Kennedy as “the first civil rights bill of the new century,” was signed into law. I had the privilege of working on GINA from the very beginning. Before GINA, it had been almost twenty years since Congress had passed civil rights legislation.¹ Indeed, GINA provides a promising departure from past civil rights laws which have been passed to correct historic injustices that have festered within American society for generations. Perhaps the most obvious example is the Civil Rights Act of 1964, which protects against discrimination based on race and gender among other categories, and which was one of the crowning achievements of the American Civil Rights Movement. GINA represents the first time that Congress has passed such legislation before the covered discrimination has become seemingly permanently ingrained in the social fabric and in that respect I think we should all be proud.

GINA- A History:

How GINA came to be enacted is a classic lesson in American politics and perseverance. By 1995 the case for Federal genetic discrimination legislation had been building. Early reports from the Congressional Office of Technology Assessment identified the potential for the misuse of genetic information for purposes of discrimination.² This was followed by a number of documented cases of genetic discrimination and several case studies which supported the credibility of many of the claims, such as those completed by CRG Board member Paul Billings.³ At the same time the Human Genome Project, one of the largest scientific research projects ever undertaken, was racing forward ahead of its goal of producing a reference sequence of the human genome. A working group associated with the Project that included CRG Board member George Annas⁴ announced model genetic discrimination legislation that same year. A number of states were already enacting legislation in this area; more than 15 states had enacted protections by 1995 and

¹ The Americans with Disabilities Act (ADA), 42 U.S.C. §§ 12101-12213 (July 26, 1990).

² See for example, U.S. Congress Office of Technology Assessment, “Genetic Monitoring and Screening in the Workplace,” OTA-BA-455 (Washington, D.C.: U.S. Government Printing Office, October 1990.)

³ See, for example Lisa N. Geller, Joseph S. Alper, Paul R. Billings, Carol I. Barash., Jonathan Beckwith and Marvin R. Natowicz, "Individual, Family, and Societal Dimensions of Genetic Discrimination: A Case Study Analysis", *Science and Engineering Ethics*, 1996, vol. 2, Issue 1.

⁴ The “Genetic Privacy Act” was announced in March 1995. It was a component of the U.S. Human Genome Project’s Ethical, Legal, and Social Issues (ELSI) working group. George Annas, Leonard Glantz, and Patricia Roche (Boston University School of Public Health) authored the proposal with funding from the DOE ELSI program.

many states were soon to follow.⁵ Many of these state laws are deficient however; they either have limited coverage or insufficient enforcement mechanisms. Many states never passed comprehensive genetic discrimination legislation. The need for a Federal standard was mounting.

In 1996 Congress passed the Health Insurance Portability and Accountability Act (HIPAA) which, among other things, prohibited the use of genetic information in certain group health-insurance eligibility decisions. New legislation was necessary to plug the holes in health insurance protections that HIPAA left behind and extend protections to other potential areas of discrimination that HIPAA wasn't designed to cover.

A number of individuals, myself included, began to raise a chorus of concern on Capitol Hill over the lack of legal protections for genetic discrimination and various media outlets began to echo them. Genetic nondiscrimination legislation was first introduced in the House of Representatives in late 1995 by Representative Louise Slaughter (D-NY), during the 104th Congress. Congresswoman Slaughter would go on to become the primary champion of genetic discrimination legislation on Capitol Hill through GINA's passage. In 1996, Senator Olympia Snowe (R-ME) and Senator Ted Kennedy (D-MA) introduced similar legislation in the Senate. Both bills specifically addressed discrimination in health insurance. Employment discrimination was not covered in this early legislation and for some in Congress, such as Senator Jim Jeffords (R-VT), it was unclear whether employment protections were necessary. Opponents to the legislation claimed that genetic discrimination in employment was already covered by the Americans with Disabilities Act (ADA), one section of which allows for a discrimination claim when an individual is regarded as disabled and discriminated against as a result. The EEOC further complicated the situation by early on supporting this interpretation of the ADA.⁶ It became clear, though, as the ADA made its rounds of court decisions that the courts were if anything taking a very limited view of the expansiveness of the ADA and it would be highly unlikely that in most cases it would be available to support a genetic discrimination claim.⁷ There certainly was no dispute that the ADA offered limited protections against the collection of genetic information. I, and others, continued to build the case that employment discrimination provisions were necessary. With our persuasion, Senator Jeffords held a Congressional hearing on genetic discrimination in the workplace⁸ and this argument eventually succeeded. Employment provisions were added shortly after to the legislation that would later become GINA.

GINA suffered in obscurity for a number of years as the result of a Republican led Congress that was hostile to adding additional restrictions on the insurance industry and employer communities. Powerful lobbies, such as the Chamber of Commerce, ensured

⁵ See the National Conference of State Legislators' (NCSL) Genetic Technologies Project database for more information on genetic discrimination state laws (<http://www.ncsl.org/programs/health/genetics.htm>).

⁶ EEOC Compliance Manual § 902, Order 915.002, 902-45 (1995).

⁷ For a more thorough discussion of this issue see Gruber, Jeremy "Genetic Discrimination and the Americans with Disabilities Act: An Unlikely Fit," http://www.workrights.org/issue_genetic/gd_ada.html.

⁸ U.S. Senate Committee on Health, Education Labor, and Pensions Committee, Committee Hearing "Genetic Discrimination in the Workplace." (July 20, 2000).

this to be the case. Despite this adversity, momentum continued to build. In 1997, I on behalf of the American Civil Liberties Union and several others representing organizations such as the Alpha-1 Association, Genetic Alliance, Hadassah, National Partnership for Women & Families and National Society of Genetic Counselors recognized the need to unite and create an equally powerful organization to fight for genetic discrimination protections. We founded the Coalition for Genetic Fairness (CGF) that same year. By the time GINA was enacted the CGF would consist of over 500 organizations.

From that day forward, the CGF became the leader of a coordinated campaign to enact genetic nondiscrimination legislation. We targeted the White House and members of the Senate and House of Representatives one by one and began to build support within Congress for genetic nondiscrimination legislation. These efforts began to bear fruit when in 2000, in my new role as legal director of the National Workrights Institute, I witnessed then President Clinton sign an Executive Order extending genetic discrimination in employment protections to Federal employees.⁹ Following this breakthrough the Senate passed genetic discrimination legislation in 2003 and 2005. The House of Representative, though, is a body more strictly controlled by majority leadership. These same years, despite growing support in the House (In 2003 and 2005 GINA had the support of 242 and 244 co-sponsors respectively) genetic discrimination legislation failed to reach the floor of the House for a vote. Support among House Republicans for this legislation was beginning to grow, though, largely as the result of the CGF working with Rep. Judy Biggert (R-IL) to become a primary co-sponsor of the legislation. It was during this time period that the CGF released a highly influential report on the issue of genetic discrimination as well.¹⁰

With more bipartisan teams in place in both the House and Senate, GINA was reintroduced in 2007. A change in party leadership in the House gave many of us hope that there would be a major breakthrough on GINA. Its fate in the House remained precarious, though, as three separate committees¹¹ maintained jurisdiction and therefore many opportunities for roadblocks existed. To overcome them, many of us worked tirelessly during this period to educate members of the appropriate House committees. Finally, the House passed GINA for the first time on April 25, 2007. Having passed the legislation twice before, most expected GINA to pass the Senate soon thereafter. But one last hurdle remained. Senator Tom Coburn (R-OK) put a hold¹² on the legislation in the Senate preventing it from coming to the floor for a vote. Coburn's Senate voting record is extremely conservative and he has a well deserved reputation for stalling measures in the Senate, to the frustration of members of both major parties. Coburn's given objection to GINA was an alleged lack of clarity on protections for embryos and fetuses, though most

⁹ Executive Order 13145 , 65 Fed. Reg. 6,877 (Feb. 10, 2000).

¹⁰ Coalition for Genetic Fairness, "Faces of Genetic Discrimination: How Genetic Discrimination Affects Real People," July 2004.

http://www.geneticalliance.org/ksc_assets/documents/facesofgeneticdiscrimination.pdf

¹¹ House Energy and Commerce Committee, House Ways and Means Committee and House Education and Labor Committee.

¹² The hold privilege is allowed by Rule VII of the Senate Standing Rules. The practice is generally used to form consensus on questionable legislation. <http://rules.senate.gov/senaterules/rule07.php>

experts did not believe this to be a legitimate concern and his hold lasted long after this issue was specifically addressed in the legislation. Support from the White House allowed Senator Coburn to become intransigent despite the White House having earlier issued a Statement of Administration Policy in support of GINA.¹³

The groundswell of support for GINA nonetheless continued to mount and the CGF put significant pressure on Senator Coburn to relent. In early 2008, Senator Coburn released his hold and on April 24, 2008 the U.S. Senate passed GINA. Finally on May 21, 2008 President Bush signed GINA into law.

What does GINA do?

GINA provides protections against genetic discrimination in both the health insurance and employment settings and puts additional limitations on the access to and disclosure of genetic information.

GINA is a relatively commonsense law. A discussion of GINA necessarily requires that we first take a look at the definition of genetic information so we can understand exactly the type of information that GINA is meant to protect. Generally, a person's genetic information is defined as information obtained from the individual's genetic tests, the individual's family member's genetic test, or the individual's family health history. A genetic test as defined by the statute is a process that analyzes human DNA, RNA, chromosomes, proteins, or metabolites, and that detects genotypes, mutations, or chromosomal changes. If the test does not detect genotypes, mutations, or chromosomal changes, or if the analysis directly relates to a health condition that could be reasonably detected without such a test, it is not considered a genetic test under GINA. The definition of genetic information includes "the occurrence of a disease or disorder in family members of the individual" because family medical history could be used to identify genetic information. GINA applies to asymptomatic individuals only. Manifested health conditions are not protected, even if they have genetic origins. The underlying genetic information, though, remains protected by GINA.

Title I of GINA deals with genetic nondiscrimination in the issuance of health insurance. Health insurance companies (including those that sell group policies to employers, non-group policies to individuals and families, and Medicare supplemental policies to Medicare enrollees) are not allowed to determine eligibility (including continued eligibility) for coverage based on genetic information, charge higher or lower premiums based on genetic information, or consider genetic information as a pre-existing condition. In addition, health insurers are prohibited from asking about genetic information as part of the application process. Once a person is covered, insurers may not ask about or use that person's genetic information for "underwriting purposes" -- for example, to determine whether to raise premiums when an individual renews his or her coverage. In this Title GINA builds on the HIPAA by extending protections to the individual market to confirm that individuals in all types of health insurance plans have the same

¹³ <http://www.whitehouse.gov/omb/legislative/sap/109-1/s306sap-s.pdf>

protections. But it goes even further than HIPAA in another important respect with regards to privacy of genetic information. One of the primary tenants of HIPAA is that there is some privacy to your health information, but to the extent that your health insurer needs that information for underwriting, they could have it; underwriting is a permitted use of health information under HIPAA. This was not a genetic specific issue. What GINA does is say that while that may be true of most health information, it is prohibited for health insurers to collect or to use your genetic health information as defined by GINA for underwriting.

Title II of GINA deals with genetic discrimination in the employment context. GINA makes it an unlawful employment practice for an employer (and applies equally to an employment agency, labor organization or joint labor-management committee controlling job training) to “fail or refuse to hire...discharge.. or otherwise to discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment” because of the genetic information of the employee. In this respect GINA adds genetic information as a protected category to the existing body of Federal civil rights law.

GINA makes it an unlawful practice for an employer to “request, require or purchase genetic information with respect to an employee or family member of an employee.” Subject to the exceptions I will discuss below, this is a total ban that will affect an employer’s ability to access such information even under circumstances where it was previously authorized under other statutes. GINA prohibits employers from requesting genetic information even in the rare case where it is arguably job related (though examples to date of such have been extremely difficult to demonstrate). Nevertheless in terms of the Americans with Disabilities Act, for example, this poses a change to how employers collect medical information at least in terms of genetic information. Under the ADA employers are authorized to collect medical information relevant to meeting a reasonable accommodation request or otherwise authorized as part of a post conditional offer of employment medical evaluation. Additionally, worker’s compensation laws would similarly be implicated.

GINA lays out six specific exceptions to the prohibition on acquisition off genetic information.

- 1) Where an employer “inadvertently requests or requires family medical history of the employee or family member of the employee.” While the chosen terms are somewhat unartful, it is clear from the intent of this exception and the legislative history of it that it is meant to address so called “water-cooler conversations” where an employee might voluntarily offer such information up to the employer.
- 2) A second exception applies to situations where an employer offers health or genetic services including a wellness program. Many employers have adopted wellness programs which begin with extensive health questionnaires. In such situations the statute requires the voluntary consent of the employee and limits access of the information obtained.

3) The third exception applies to the genetic monitoring of the biological effects of toxic substances. Some employers have programs which conduct genetic tests of workers in specific hazardous environments to determine if they need to be reassigned before they become symptomatic of adverse exposure. GINA now requires this testing to be voluntary.

4) Additional exceptions include Federal or state Family and Medical Leave Act compliance, commercially and publicly available records (but not medical databases and court records) and law enforcement purposes.

GINA requires that genetic information be kept as part of the employee confidential medical record and prohibits the disclosure of genetic information unless:

1) There is a written request of an employee for such information (or a family member if the family member is receiving a genetic service).

2) To a health researcher in compliance with applicable law

3) In response to a court order but only if the genetic information is specifically authorized and only with the knowledge of the employee.

4) FMLA compliance and information of a manifested disease or disorder that poses an imminent hazard of death or life threatening illness.

GINA maintains strong enforcement mechanisms in both Titles consistent with existing law in their respective areas

The sophistication of many subjects does not lend themselves well to comprehensive legislation. Therefore in these cases the Congress will designate Federal agencies for additional rulemaking. As of this writing agencies charged with administering GINA are undertaking the rulemaking process.¹⁴ While such rules do not have the same standing as law, they are highly influential. My first act as President of the Council for Responsible Genetics was to testify before the Commissioners of the Equal Employment Opportunity Commission for strong regulations and I continue to work on comments to address lingering concerns. As this process unfolds we are sure to learn even more about GINA. Much of these regulations will center on further clarifying key terms. My hope is that they will do so in a strong and unambiguous manner. They will also discuss in more detail the affirmative steps that covered entities (be they insurers or employers) will need to take to remain in compliance with GINA and how both Titles will interact. Finally they will further define the exceptions in Title II on the prohibition of collection of genetic information. It is our hope and expectation that they will construe these exceptions narrowly to be consistent with the intent of Congress.

¹⁴ The Departments of Treasury, Labor, and Health and Human are charged with enforcing various aspects of Title I of GINA and the Equal Employment Opportunity Commission is charged with enforcing Title II.

Conclusion:

Bismarck said well over a hundred years ago that “politics is the art of the possible.” GINA provides strong new protections for all Americans against discrimination and access to genetic information but to pass any law involves compromise. GINA, for example, does not address genetic discrimination in life insurance, disability insurance, or long-term care insurance. Nor does GINA address other, at least theoretical, areas where there might be genetic discrimination in the future. Certainly many of us who worked on GINA regret dearly that GINA does not protect symptomatic individuals. The inclusion of this class of individuals would have brought up a larger debate on the limitations of the Americans with Disabilities Act because in many cases the extent of their condition would not be significant enough to qualify for its protections. It would also have implicated an ethical debate on “genetic exceptionalism” by offering protections to symptomatic individuals with genetic conditions but not to individuals for whom no such linkage could be demonstrated. There was no support in Congress for these discussions and they would have derailed GINA.

No single law solves every issue that it might implicate. The Civil Rights Act of 1964 was no less a watershed moment in the history of our country because it didn't cover discrimination in housing or based on age and disability. These protections came later. Nor was the Civil Rights Act of 1964 any less diminished because it remains ineffective at addressing areas where race and gender discrimination remain institutionalized in this country from education to the criminal justice system. Similarly GINA is a strong and essential first step in the fight against genetic discrimination and misuse of medical information more generally but it is not our last battle. The precedent of GINA as well as the level of education on Capitol Hill as the result of the process of enacting GINA, will allow us to build upon the foundation that GINA now provides. We must continue to seek out and address discrimination in every corner and ensure that strong protections are in place to address it.