

Do Statutes Enable Genetic Discrimination?

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Introduction

In recent years, advancements in personal medicine and genetics research have significantly outpaced expectations and these scientific advancements are now on the precipice of becoming widely employed throughout the healthcare industry. Cost of sequencing a genome has drastically fallen to around \$1000 per genome (Nature 507, 294-295, 20 March 2014).¹ With such information at hand, researchers and medical professionals can explore creating highly personalized medicines such as Kalydeco, a medication that works by addressing the mutations of genes that result in cystic fibrosis, and thus treat the underlying cause of the disease itself rather than the symptoms.²

Personalized medicine is a "field of healthcare that is informed by each person's unique clinical, genetic, genomic, and environmental information"³ used to create treatments or assessments that are unique to an individual. For example, "treatment with vitamin B₁₂ is beneficial for some subsets of patients with anemia but has no benefit for the remainder"⁴. By identifying the patients in which treatment would be effective the

¹ E. C. Hayden, *Technology: the \$1,000 genome*. 570 Nature 7492, 294-295 (March 19, 2014), <http://www.nature.com/news/technology-the-1-000-genome-1.14901>.

² T. Simoncelli, *Paving the way for personalized medicine: FDA's role in a new era of medical product development*, U.S. Food and Drug Administration (October 2013).

³ *Personalized medicine*, U.S. News and World Report Health (Jan. 20, 2011), <http://health.usnews.com/health-conditions/cancer/personalized-medicine/overview>

⁴ J. L. Mega, *Population and personalized medicine in the modern era*, The Journal of the American Medical Association, (November 19, 2014).

patients can be efficiently treated. By analyzing individuals and their specific illnesses, personalized medicine can create a much more effective treatment than a medication that would work on many but with lower efficiency or strength. Personalized medicine also greatly benefits from the rapidly increasing amount of biomedical data through data capture and data sources. Information about new findings can spread easily and numerous studies across different locations increase the overall body of knowledge. As one example, the "UK Biobank has obtained around half a million people's blood, urine, and saliva samples for molecular analysis."⁴

With the advancements in personalized medicine and genetic research, however, there will be an inevitable clash involving politics, the justice system, and personal rights. The law typically lags behind the issues that occur with the introduction of new technology. A recent Congressional Research Service (CRS) report for Congress stated that, aside from proposed revisions to existing laws, "there have been no major cyber security legislation changes enacted since 2002".⁵ If this kind of lag extends to the medical field then, with the inevitable increasing interactions between technology and healthcare, legal problems will appear that must address the increasingly novel and highly personal technological approaches of the healthcare services being introduced.

Combined with the lowered costs of genomic sequencing, there are new healthcare services that are becoming widely available, such as genetic test, after the Supreme Court's ruling that human genes could not be patented. This decision knocked down

⁵ E. A. Fischer, *Federal laws relating to cybersecurity: overview and discussion of proposed revisions*, Congressional Research Service (2013), <https://fas.org/sgp/crs/natsec/R42114.pdf>.

many of the monopolies held by pharmaceutical companies⁶. Other than side effects and physical concerns, employing personalized medicine carries the risk of being subject to 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"⁷. Genetic discrimination can also be considered to be unfair treatment of an individual by employers or by health insurance providers once the individual is determined to have a genetic disorder, predisposition to a genetic disorder, or, in some cases, be a carrier of a genetic disorder in spite of not exhibiting symptoms.

The Emergence of Statutory Provisions

To address the problem of genetic discrimination and lack of a unified stance on the legalities of such discrimination, several important statutes were passed and put into action. This paper will mainly discuss the Genetic Information Nondiscrimination Act of 2008 (GINA) and of its relation to both the Americans with Disabilities Act (ADA) and the Patient Protection and Affordable Care Act (PPACA), more commonly known as the Affordable Care Act (ACA) or "Obamacare". All statutes offer some measure of protection against genetic discrimination but they are fairly recent and, at times, underutilized. Some statutes do not offer very extensive or effective protection. This paper will explore and analyze these statutes and their effectiveness, especially noting areas where one statute is lacking and which statute makes up for

⁶ A. Pollack, *After patent ruling, availability of gene tests could broaden*, New York Times, (June 13, 2013), http://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html?pagewanted=all&_r=0.

⁷ *Genetic Information Nondiscrimination Act of 2008*, National Human Genome Research Institute, (last updated July 31, 2014), <http://www.genome.gov/10002077#al-2>.

the deficiency. The following cases are those that are relevant to genetic discrimination and will be used to illustrate the statutes used before the passing of GINA and the extent to which such statutes have been used.

Before laws were enacted to specifically address genetic discrimination, the Equal Employment Opportunity Commission (EEOC) filed a lawsuit against Burlington Northern Santa Fe (BNSF) Railroad, which had been conducting genetic testing on its employees without the workers' knowledge.⁸ The EEOC argued that the testing being conducted as a condition for employment was illegal and violated the Americans with Disabilities Act (ADA).⁹ BNSF Railroad continued to deny violating the ADA but did agree to consensual mediation.

To address the issue of genetic discrimination the first major civil rights act of the 21st century, the Genetic Information Nondiscrimination Act (GINA), was signed into law in 2008. "GINA has two parts to it: Title I prohibits genetic discrimination by health insurance providers and Title II prohibits genetic discrimination by employers."¹⁰ On May 7, 2013 the EEOC filed a lawsuit on behalf of employee, Rhonda Jones, over an illegally rescinded offer of employment after the employer claimed that Ms. Jones' health test results showed carpal tunnel syndrome, even though Ms. Jones' personal physician indicated otherwise. The defendant, Fabricut Inc., violated GINA by requesting family

⁸ *EEOC and BNSF settle genetic testing case under American with Disabilities Act*, U.S. Equal Employment Opportunity Commission, (May 8, 2002), <http://www.eeoc.gov/eeoc/newsroom/release/5-8-02.cfm>.

⁹ *Cases of genetic discrimination*. National Human Genome Research Institute, (September 23, 2014), <http://www.genome.gov/10002077>.

¹⁰ *What is genetic discrimination?* Genetics Home Reference (November 11, 2014), <http://ghr.nlm.nih.gov/handbook/testing/discrimination>.

medical history and eventually settled to pay \$50,000.¹¹

Statute Provisions

In the years that followed after GINA was signed into law, only 0.2% in 2010 and 2011 to .04% in 2014 of all charges filed with the EEOC were filed under GINA¹². Only with the EEOC v Fabricut, Inc. case in 2013 would the EEOC file the first lawsuit that clearly alleged genetic discrimination. This problem is coupled with the fact that an increasing lack of support by the EEOC exists when dealing with cases that involve dismissal from a position based on discrimination in general. "Between 2008 and 2012, nearly a third of all cases were dismissed by the EEOC without an investigation or a hearing."¹³ One of the many reasons that the cases were dismissed was mistakes by the agency where "small negative actions were considered inconsequential."¹⁴

Even though each state has its own measure of protection against genetic discrimination, the amount of protection varies. Some states offer more stringent coverage than GINA while other

¹¹ *Fabricut to pay \$50,000 to settle EEOC disability and genetic information discrimination lawsuit*, U.S. Equal Employment Opportunity Commission, (May 7, 2013), <http://www.eeoc.gov/eeoc/newsroom/release/5-7-13b.cfm>.

¹² *Charge Statistics FY 1997 Through FY 2014*. U.S. Equal Employment Opportunity Commission, <<http://eeoc.gov/eeoc/statistics/enforcement/charges.cfm>>.

¹³ E. Katz, *Agencies are increasingly dismissing discrimination claims for the wrong reasons*, Government Executive, (September 15, 2014), <http://cdn.govexec.com/interstitial.html?v=2.1.1&rf=http%3A%2F%2Fwww.govexec.com%2Fmanagement%2F2014%2F09%2Fagencies-are-increasingly-dismissing-discrimination-claims-incorrectly%2F94118%2F>.

¹⁴ *Fabricut to pay \$50,000 to settle EEOC disability and genetic information discrimination lawsuit*, U.S. Equal Employment Opportunity Commission, (May 7, 2013), <http://www.eeoc.gov/eeoc/newsroom/release/5-7-13b.cfm>.

states provide less. GINA attempts to create some national baseline that provides the minimum degree to which state laws must abide. To better understand the Genetic Information Nondiscrimination Act of 2008, consider what genetic information consists of under GINA. Genetic information is considered as information on any genetic test of an individual, an individual's family up to 4th degree relatives, and any embryos. Genetic information also includes family medical history and genetic services, such as clinical trials or genetic counseling. However we should note that whether that service was requested by the individual or a relative still places the knowledge of the genetic service under protection of GINA.¹⁵

Further exploration of the extent to which Title I and Title II offer protection to an individual reveals that under Title I, health insurance providers are prohibited from genetic discrimination and are also prohibited from adjusting premium costs of health plans by using one member's genetic information as evidence against other members of the group. GINA also prohibits ". . . a group health plan from collecting genetic information for underwriting purposes."¹⁶ And with underwriting being defined as:

- *"Under GINA, the definition of underwriting purposes is broader than merely activities relating to rating and*

¹⁵ "GINA" *Genetic information nondiscrimination act of 2008; information for researchers and healthcare professionals*, Department of Health and Human Services , (April 6, 2009), <http://www.genome.gov/pages/policyethics/geneticdiscrimination/ginainfodoc.pdf>

¹⁶ *FAQs on the Genetic Information Nondiscrimination Act*, U. S. Department of Labor, <http://www.dol.gov/ebsa/faqs/faq-GINA.html>, (last visited March 26, 2015).

pricing a group policy. Under GINA, underwriting purposes means, with respect to a group health plan:

- *Rules for or determination of eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program);*
- *Computation of premium or contribution amounts under the plan (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing an HRA or participating in a wellness program);*
- *The application of any preexisting condition exclusion under the plan; and*
- *Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits."*¹⁷

Under Title II, employers are not allowed to collect genetic information on current or potential employees. Collect being defined as require, request, or purchase.¹⁸ Employers are also not allowed to make employment decisions using genetic information.

Questionable Effectiveness of Statues

Now with this overview of GINA several gaps may be noted. For one, although health care providers are prohibited from genetic discrimination they are given some liberties under certain

¹⁷ *FAQs on the Genetic Information Nondiscrimination Act*. United States Department of Labor, <http://www.dol.gov/ebsa/faqs/faq-GINA.html>, (last visited March 26, 2015).

¹⁸ *Id.*

conditions. For example, if a health plan ties payment of procedures to the necessity of those procedures, and if those procedures are directly relevant to a person's genetic makeup, then the plan may demand that the patient take a genetic test or else be refused payment. Payment is also subject to the results of the genetic test. Furthermore, GINA does not cover several different types of insurance; life insurance, disability insurance, and long-term care insurance are not covered. In regards to Title II and employers, there are also several conditions. GINA does not apply to private employers with less than 15 employees due to the limitations set by Title VII of the Civil Rights Act in 1964 which states:

"(a) Employer practices

It shall be an unlawful employment practice for an employer

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- (1) to fail or refuse to hire or to discharge any individual, or otherwise to discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's race, color, religion, sex, or national origin; or*
 - (2) to limit, segregate, or classify his employees or applicants for employment in any way which would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect his status as an employee, because of such individual's race, color, religion, sex, or national origin.*

And with "employer" defined as:

"The term "employer" means a person engaged in an industry affecting commerce who has fifteen or more

employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year,"¹⁹

Employers that are subject to GINA may at times acquire genetic information under the following six exceptions:

- Inadvertent acquisitions of genetic information
- Genetic information obtained as part of health or genetic services offered by the employer on a voluntary basis
- As part of the certification process where an employee is asking for leave to care for a family member with a serious health condition.
- Genetic information acquired through commercially and publicly available documents as long as the employer is not searching those sources with the intent of finding genetic information
- Genetic information may be acquired through a genetic monitoring program that monitors the biological effects of toxic substances in the workplace where the monitoring is required by law or, under carefully defined conditions, where the program is voluntary.
- Acquisition of genetic information of employees by employers who engage in DNA testing for law enforcement purposes as a forensic lab or for purposes of human remains identification is permitted, but the genetic information may only be used for analysis of DNA markers for quality control to detect sample contamination.²⁰

Detailed analysis of the above conditions is warranted as they are especially important because while some of the conditions

¹⁹ Civil Rights Act of 1964 § 7, 42 U.S.C. § 2000e (1964).

²⁰ *Genetic Information Discrimination*. U.S. Equal Employment Opportunity Commission, <<http://www.eeoc.gov/laws/types/genetic.cfm>>.

are understandable exceptions, others provide several loopholes within GINA that would allow collection of genetic information without penalty. In an interview with Mark A. Rothstein, JD, Herbert F. Boehl Chair of Law and Medicine and Director of the Institute for Bioethics, Health Policy and Law at the University of Louisville School of Medicine, Mr. Rothstein is asked how effective he finds GINA to be in protecting people from genetic discrimination. In Mr. Rothstein's reply he describes several of these loopholes that exemplify the shortcomings of GINA:

- *"....Let's say I apply for an individual health insurance policy. If I have a genetic predisposition to prostate cancer, a family history of prostate cancer, or a brother who tested positive for a gene that increases the risk for prostate cancer, I couldn't be denied coverage under GINA. But if 2 years from now, I develop prostate cancer, does GINA protect me? No, because GINA applies only to people who are asymptomatic.*
- *Another problem with GINA is in the employment setting. The law attempts to prevent discrimination by limiting the information that's available to employers. But there is no practical way to do this.*
- *For example, under the Americans With Disabilities Act, after an individual is made a conditional offer of employment, the employer can say, 'Your references check out, and you have just the background we want. I'm prepared to make you an offer to start August 1, but it's conditional on your getting approval on your medical examination.' That's lawful. As a condition of employment, the employer could make an individual sign an*

authorization to turn over his or her health records to the medical examiner of the company."²¹

He summarizes GINA in the following words:

- *"To sum up, then, there are 2 main problems with GINA: It doesn't cover enough situations, and even when it does cover a situation -- for example, health insurance and employment -- it is not adequate."*²²

The numerous exceptions to GINA above illustrate the reasoning behind GINA. GINA was not created with the intention of ending or quelling genetic discrimination but with the intention of allowing people to be treated without fear of negative consequences although a person's best interests may lie in having genetic testing done, the resulting discrimination by employers and health insurance providers prove to be more damaging. GINA's effectiveness in reducing negative consequences attributed to genetic discrimination is extremely suspect. As mentioned by Mr. Rothstein, there are many faults in GINA since GINA only focuses on such a limited section within employment and health insurance and does not provide a measure of protection against other forms of genetic discrimination that may occur, such as discrimination for eligibility for other types of insurance.

Furthermore GINA has been slow in its establishment since it is considered a 2008 act, but only took effect officially November 21, 2009. Aside from that, the Final Rules for its implementation were not issued until another year later by the

²¹ M.A. Rothstein and L. E. Walker, *Are genetic discrimination laws up to the task?* Medscape Genomic Medicine, (August 8, 2012), <http://www.medscape.com/viewarticle/768560>.

²² Id.

EEOC, in November 9, 2010. The Final Rules did not take effect until January 10, 2011²³. GINA was not solidified until two years after it was signed into law on May 21, 2008 by then-President George W. Bush.

Interaction Between Different Statutes

GINA's incomplete coverage creates cases that concern genetic discrimination in the workplace that, at times, fall under the Americans with Disabilities Act (ADA) and, at other times, under the Genetic Information Nondiscrimination Act (GINA). ADA covers individuals with severe illnesses that are related to genetic disorders that severely impair the individual while GINA concerns asymptomatic individuals²⁴. Both acts cover the opposite sides of the spectrum but not the ambiguous middle. Individuals who are not majorly impaired but still exhibit symptoms would then not be protected by the Genetic Information Nondiscrimination Act, nor the Americans with Disabilities Act.

On the other spectrum concerning health care insurance providers, however, the Affordable Care Act prevails where GINA and the ADA does not. With the introduction of the Affordable Care Act, under the Pre-existing Condition Insurance Plan (PCIP),

²³110th Congress Public Law 233, U.S. Government Printing Office, <http://www.gpo.gov/fdsys/pkg/PLAW-110publ233/html/PLAW-110publ233.htm>, (last visited March 31, 2015).

²⁴M.A. Rothstein, *GINA, the ADA, and genetic discrimination in employment*. *Journal of Law, Medicine, and Ethics*, 36 *The Journal of Law, Medicine, and Ethics* 4, 837-840 (Winter 2008), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3035561/>.

insurance plans will open up²⁵ and children under nineteen can no longer be denied coverage for preexisting conditions since the ACA also "Ends Pre-Existing Condition Exclusions for Children."²⁶ Insurance providers will not be allowed to deny coverage due to preexisting conditions and simultaneously be prevented from canceling coverage after symptoms of disease appear. In essence, this arrangement will cover the middle ground left by the ADA and GINA.

While GINA prohibits discriminatory practices by health insurance providers among asymptomatic patients, the ACA prohibits genetic discrimination among patients that manifest the disease at later times. The ACA offers a much more extensive body of law regarding genetic discrimination and health insurance eligibility than the baseline protection that GINA establishes. In a Congressional Research Service (CRS) report, the authors speculate, "While the ACA creates criteria for premium rates, GINA prohibits premium adjustments based on genetic information."²⁷ Though this is seemingly contradictory, they are quick to also mention, "Though one may argue that Section 2701 of the PHSA renders GINA, at least in part, ineffective and therefore amends or repeals GINA by implication, given that amendments by implication are disfavored, and without a

²⁵ *About the new Pre-Existing Condition Insurance Plan*, The Center for Consumer Information & Insurance Oversight, Centers for Medicare and Medicaid Services, (July 23, 2012), <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/>.

²⁶ About the law, HHS.gov/Health Care, U.S. Department of Health and Human Services, (November 14, 2014), <http://www.hhs.gov/healthcare/rights/>.

²⁷ J.V. DeBergh, A.K. Sarata, & J. Staman. *The Genetic Information Nondiscrimination Act of 2008 and the Patient Protection and Affordable Care Act of 2010: overview and legal analysis of potential interactions*, Congressional Research Service, (December 21, 2011), https://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/CRS_GINA_and_ACA.pdf.

demonstrated clear intention to override its provisions, a court may be more likely to dismiss this argument."²⁸

The passing of three statutes which all have relevance to genetic discrimination in increasingly close succession shows increasing attention being given to this area. The Americans with Disabilities Act was passed in 1990. Then the Genetic Information Nondiscrimination Act was passed in 2008. Most recently, the Patient Protection and Affordable Care Act was signed in 2010 by President Barack Obama. There is a decreasing amount of time between laws passed that either reference genetic discrimination or deliberately address it. Although no single statute is comprehensive, the entire body of statutes itself is beginning to cover a wider field. The ADA is used for the workplace and with unfair employers' practices, the ACA is a much deeper, more specific statute that concerns health insurance, and GINA creates a minimum set of regulations and criteria for state laws, employers, and health insurance providers.

With this increasing attention towards the role of genetic tests and technology in law and society, we should expect to see an increase in legal reform toward our current laws dealing with genetic discrimination. Although in this case, the law has attempted to address the problem in its early stages. Its first attempt with GINA was not to combat genetic discrimination so much as to encourage people to conduct genetic testing without consequence, thus creating a rather weak statute with many loopholes. We see the law becoming more aggressive and solid with the passing of the ACA as the law makes several significant steps by prohibiting denial of coverage based on pre-existing conditions.

²⁸ Id.

Conclusion

Personalized medicine is only going to advance and increase in usage. The FDA's guidance documents have reflected this with growing rates of documents addressing the latest breakthroughs with each passing year. The laws or reforms that will come to pass will also have to anticipate the kind of progress that will be made in future years. To truly combat genetic discrimination, GINA will need to be more practical in its criteria of the handling of individuals' genetic information records and to have provisions for the numerous loopholes. Concerning employers, either GINA must be strengthened or given more authority on the matter or the ADA has to refine its criteria concerning people who fall under it. The ACA is still new enough that its strengths and flaws concerning genetic information are still difficult to observe without precedent cases since it covers health care insurance. We do not know the extent to which new procedures will create loopholes in its regulations. Lawmakers will need to be very wary that the incoming advancements in personalized medicine do not create a GINA out of the ACA.