ESSAY

GENETIC INFORMATION NON-DISCRIMINATION ACT

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The Genetic Information Non-Discrimination Act ("GINA") was hailed as the "first civil rights bill of the new century" when it passed in 2008.[1] *This groundbreaking legislation protects Americans from employer and insurance discrimination based on genetic information and encourages participation in genetic testing and genetic research. This Article discusses the challenges faced over the thirteen years it took to pass the legislation, and the future directions this country might take to expand on GINA's guiding principles. As with all advances in civil rights, the battle is far from over—more must be done to protect Americans against discrimination.*

I. INTRODUCTION

A. Challenges in the Genomic Era

In 1995, the year I first introduced legislation to address genetic discrimination, the genomic era was still in its burgeoning stages. The human genome had not yet been fully sequenced, and the potential for personalized medicine had not yet been realized. The future for advances in genomic-based medicine held both promise and trepidation for the American people. Surveys showed that while "[t]he majority of Americans enthusiastically support[ed] genetic testing for research and health care . . . a large majority (92%) also express[ed] concern that results of a genetic test could be used in ways that are harmful."[2] Evidence was mounting that Americans were already subjected to genetic discrimination,[3] and without protective legisla-

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[1] Press Release, U.S. Senate Comm. on Health, Educ., Labor, & Pensions, Kennedy, Enzi, Snowe Celebrate Passage of Genetic Information Nondiscrimination Act (Apr. 24, 2008) (quoting Sen. Kennedy (D-Mass.)), http://www.help.senate.gov/newsroom/press/release/?id=313bfde8-f967-46b4-aa9d-11bc73728813.

[2] GENETICS & PUB. POLICY CTR., U.S. PUBLIC OPINION ON USES OF GENETIC INFORMATION AND GENETIC DISCRIMINATION 2 (2007), *available at* http://www.dnapolicy.org/resources/GINAPublic_Opinion_Genetic_Information_Discrimination.pdf.

[3] *See generally*, NAT'L P'SHIP FOR WOMEN & FAMILIES, FACES OF GENETIC DISCRIMINATION: HOW GENETIC DISCRIMINATION AFFECTS REAL PEOPLE (2004), *available at* http://www.nationalpartnership.org/site/DocServer/FacesofGeneticDiscrimination.pdf?docID=971.

tive action, their ranks would only grow. Furthermore, due to fear of discrimination, people shied away from participation in research studies[4]—the very research that could benefit human health.

At the time, no federal laws addressed discrimination based on genetic information in a comprehensive fashion. While certain federal statutes protected specific types of health and personal information,[5] substantial gaps and inconsistencies remained with respect to genetic discrimination by health insurers and employers. In order to encourage the tremendous potential of genomic medicine for rapid advancement in technology and human health, Congress needed to pass legislation to protect the rights of citizens. As Thomas Jefferson so aptly stated in 1816, in a quote that is now inscribed on the Jefferson Memorial in Washington, D.C.:

> Laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths disclosed, and manners and opinions change with the change of circumstances, institutions must advance also, and keep pace with the times.[6]

Given the exponential progress of genomic technology and discovery, keeping pace with the times was a growing challenge for lawmakers, who are most often not equipped with a background in the advanced science of genetics. Such limitations in knowledge had to be bridged in order to make informed policy decisions. In addition, competing interests on the part of health insurance companies and businesses posed significant challenges in building support for legislation on genetic information. For these reasons, I championed GINA for thirteen years. It was a long and arduous process, but ultimately successful. GINA now protects Americans from employer and health insurance discrimination based on genetic information, thus encouraging genetic testing and participation in research studies.

B. Genomic Research and Genetic Tests

The Human Genome Project ("HGP") was first proposed to Congress in 1990 by the Department of Energy ("DOE") and the National Institutes of Health ("NIH") as part of an ambitious interagency endeavor to map and sequence the complete human genome.[7] It was hoped that by sequencing and

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[4] *See, e.g.*, *id.* at 9.

[5] *See, e.g.*, Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified at scattered sections of 29 U.S.C. & 42 U.S.C.); Americans With Disabilities Act (ADA) of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified at scattered sections of 42 U.S.C. & 47 U.S.C.).

[6] To Samuel Kercheval (July 12, 1816), *in* 12 THE WORKS OF THOMAS JEFFERSON IN TWELVE VOLUMES, at 12 (Paul L. Ford ed., Federal ed. 1905) (1905).

[7] U.S. Dep't of Energy, *About the Human Genome Project*, HUMAN GENOME PROJECT INFORMATION, http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml (last modified Sept. 19, 2011).

characterizing the genome we would further our understanding of human genetics, as well as the role of genes in health and disease.[8] The results from this project were expected to shape the future of biological and biomedical research.[9]

Even before the completion of the HGP, scientists had made great advances in genetic research, identifying more than 6,000 single-gene disorders, or diseases caused by a single genetic mutation, including cystic fibrosis, sickle cell anemia, Huntington's disease, and muscular dystrophy.[10] A number of genetic tests were available that could provide individuals with information about their likelihood of contracting a disease or developing a health condition. For example, Huntington's disease is passed from parent to child through a genetic mutation or misspelling of a normal gene.[11] This genetic mutation is dominant, which means that if an individual carries just one copy of the defective gene, that person will contract the neurodegenerative disorder.[12] It also means that any child of an affected person has a 50% chance of inheriting the disease.[13]

However, most genetic-based health conditions are not so straightforward. As researchers have learned over the years, disease is rarely a simple gene-to-symptom phenomenon. Instead it is often the result of complex interactions of many different genes as well as environmental factors.[14] Carrying a given genetic mutation does not guarantee that one will fall ill; a genetic flaw simply confers a level of higher or lower risk upon the carrier.[15] Moreover, our limited understanding of genetic risk and its interplay with other factors, such as environmental exposures that may either increase risk or protect against it, make it exceedingly difficult to predict with certainty what a given genetic defect means for an individual. Fully understanding how the genome affects human health will take much future work.

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[8] *See* U.S. Dep't of Energy, *Medicine and the New Genetics*, HUMAN GENOME PROJECT INFORMATION, http://www.ornl.gov/sci/techresources/Human_Genome/medicine/medicine.shtml (last modified Sept. 19, 2011).

[9] *Id.*

[10] U.S. Dep't of Energy, *Genetic Disease Information*—Pronto!, HUMAN GENOME PROJECT INFORMATION, http://www.ornl.gov/sci/techresources/Human_Genome/medicine/assist.shtml (last modified Mar. 7, 2012).

[11] *NINDS Huntington's Disease Information Page*, NAT'L INST. OF NEUROLOGICAL DISORDERS AND STROKE (Aug. 13, 2010), http://www.ninds.nih.gov/disorders/huntington/huntington.htm.

[12] *Id.*

[13] *Id.*

[14] U.S. Dep't of Energy, *supra* note 10.

[15] *The National Institutes of Health: Decoding our Federal Investment in Genomic Research: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 108th Cong. 14–15 (2003) (statement of Dr. Francis S. Collins, Dir. of the Nat'l Human Genome Research Inst.).

After thirteen years of work and $3 billion of investment, sequencing of the human genome was completed in 2003[16]—fifty years after the publication of Watson and Crick's seminal 1953 paper on the structure of the DNA double-helix, the molecule that encodes genetic information from one generation to the next.[17] Completion of the HGP may very well be the most momentous medical achievement in this century, with unparalleled implications for public health and modern medicine. Researchers are now using this wealth of data to link genetic markers to human diseases and health conditions, helping to guide diagnoses as well as treatment and prevention strategies.[18] And this is only the beginning.

C. Genetic Discrimination and Public Perception

Each of us is thought to carry dozens of glitches in our DNA.[19] Single-gene disorders alone are estimated to occur in 1 out of every 200 births.[20] Complex genetic disorders such as heart disease, high blood pressure, Alzheimer's disease, cancer, and diabetes represent the majority of the 15,500 recognized genetic disorders afflicting 13 million Americans.[21] Given the prevalence of genetic mutations, any one of us could have a predisposition for a genetic disorder. The availability of genetic tests for some of these predispositions has clear benefits for treatment and prevention strategies.[22] Despite the uncertainties and complexities that come with genetic testing, this information was also of great interest to third parties such as employers and health insurers, who were concerned about the negative effects of genetic diseases on the productivity of employees or the cost for treatment of beneficiaries.[23] Surveys showed that while the majority of Americans enthusiastically supported genetic testing for research and health care purposes, a large majority (92%) also expressed concerns that results of genetic tests could be used in harmful ways.[24]

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[16] U.S. Dep't of Energy, *The Department of Energy and the Human Genome Project Fact Sheet*, HUMAN GENOME PROJECT INFORMATION, http://www.ornl.gov/sci/techresources/Human_Genome/project/whydoe.shtml (last modified May 12, 2011).

[17] *See generally* J.D. Watson & F.H.C. Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953).

[18] *The National Institutes of Health: Decoding our Federal Investment in Genomic Research*, *supra* note 15, at 14.

[19] *Genetic Information in the Workplace: Hearing Before the S. Comm. on Health, Educ., Labor, and Pensions*, 106th Cong. 7 (2000) (statement of Dr. Francis S. Collins, Dir. of the Nat'l Human Genome Research Inst.).

[20] U.S. Dep't of Energy, *supra* note 10.

[21] Genetics Education Center, *Prevalence of Genetic Conditions / Birth Defects: A Variety of References*, UNIV. OF KAN. MED. CTR., http://www.kumc.edu/gec/prof/prevalnc.html (last visited Oct. 6, 2012).

[22] *The National Institutes of Health: Decoding our Federal Investment in Genomic Research*, *supra* note 15, at 14.

[23] AMANDA K. SARATA & ERIN D. WILLIAMS, CONG. RESEARCH SERV., RL33903, GENETIC DISCRIMINATION: OVERVIEW OF THE ISSUE AND PROPOSED LEGISLATION 1, 6, 13 (2008).

[24] GENETICS & PUB. POLICY CTR., *supra* note 2, at 2.

Opponents of Congressional action to address this problem argued that legislation was premature given that genetic discrimination was relatively infrequent.[25] I would argue that even a rare discrimination event should not happen, and cases had already been documented. In the 1970s, African-Americans were targeted for genetic testing for sickle cell disease, a genetic blood disorder.[26] Test results were not kept confidential and led to stigmatization and discrimination by employers and health insurance companies.[27] In 1998, a court ruled that Lawrence-Berkeley Laboratories had violated the privacy rights of its employees by performing tests for syphilis, sickle cell genetic markers, and pregnancy without their knowledge or consent over a twenty-five-year period.[28] In 2000, Gary Avary, an employee of the Burlington Northern Santa Fe Railroad, discovered that his employer had administered genetic tests for carpal tunnel predisposition on employees without their knowledge or consent.[29] The U.S. Equal Employment Opportunity Commission ("EEOC") settled this case in court by challenging the use of workplace genetic testing under the Americans with Disabilities Act of 1990 ("ADA"). Speaking of his experience, Mr. Avary stated that:

> What happened to me should not happen to anyone, especially in the United States. It is a direct infringement on our fundamental right to be who we are. No one can help how they are put together, only God knows that. The employer, the insurance company or anyone else has no business of that knowledge. That information . . . should not be used against you and your family for hiring and firing practices, or acceptance and/or denial into insurance programs.[30]

These examples are only a handful of the dozens of genetic discrimination cases that had been documented.[31] A study in 1996 by the Genetic Alliance, a coalition of more than 600 special interest groups, found that thirteen percent of respondents reported that they believed they or relatives had been

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[25] Kathy L. Hudson et al., *Keeping Pace with the Times—The Genetic Information Non-Discrimination Act of 2008*, 358 NEW ENG. J. MED. 2661, 2661 (2008).

[26] Howard Markel, *Scientific Advances and Social Risks: Historical Perspectives of Genetic Screening Programs for Sickle Cell Disease, Tay-Sachs Disease, Neural Tube Defects and Down Syndrome, 1970-1997*, PROMOTING SAFE AND EFFECTIVE GENETIC TESTING IN THE UNITED STATES (Apr. 2006), http://www.genome.gov/10002401.

[27] *Id.*

[28] Norman-Bloodsaw v. Lawrence Berkeley Lab., 135 F.3d 1260 (9th Cir. 1998).

[29] *See* Equal Emp't Opportunity Comm'n v Burlington N. & Santa Fe R.R. Co., No. 02-C-0456, 2002 WL 32155386 (E.D. Wis. May 8, 2002).

[30] *Genetic Non-Discrimination: Implications for Employers and Employees: Hearing Before the Subcomm. on Emp'r-Emp. Relations of the H. Comm. on Educ. and the Workforce*, 107th Cong. 8-9 (2001) (statement of Gary Avary, Employee, Burlington Northern Santa Fe Railroad Company).

[31] *See generally* COUNCIL FOR RESPONSIBLE GENETICS, GENETIC DISCRIMINATION: POSITION PAPER (2001).

denied jobs or dismissed from them because of genetic conditions.[32] Such perceived abuses fed a growing public fear of genetic discrimination, leading many Americans to forgo genetic testing even if early detection of a genetic predisposition could have provided beneficial health information.[33] Even a majority of genetic counselors surveyed—those well-versed in the policies and protections of the law—reported they would not bill their insurance companies for a genetic test due to fear of discrimination.[34] Twenty-six percent responded that they would use an alias to obtain a genetic test so as to reduce the risk of discrimination and maximize confidentiality.[35] Such fears were not unsubstantiated. A 2007 study on medical underwriting indicated that a percentage of health insurance applicants were denied coverage, administered a surcharge on premiums, or given limited coverage benefits based on genetic information.[36]

Genetic discrimination is not acceptable in the United States. No one should be stigmatized or discriminated against because of genetic predispositions that we all may carry. People should be free to know their own genetic predisposition to diseases for purposes of early treatment and lifestyle changes such as diet, exercise, or changes in environment, without being concerned that they will be discriminated against based on this information. As Francis Collins, leader of the HGP and now Director of the National Institutes of Health, stated, "Genetic information and genetic technology . . . can be used in ways that are fundamentally unjust. . . . Already . . . people have lost their jobs, lost their health insurance, and lost their economic well-being . . . due to the unfair and inappropriate use of genetic information."[37]

However, without protections in place, there is always a risk that individuals will be discriminated against by their employer or insurance company. The idea of legislation creating such protections was supported by the general public.[38] A 2004 survey indicated that eighty percent of respondents opposed allowing health insurers access to their genetic information.[39] Over ninety percent of respondents felt that employers should not have access to this information.[40] According to a 2006 survey by Cogent Research, seventy-two percent of Americans agreed that the government should establish laws

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[32] E. Virginia Lapham, Chahira Kozma, & Joan O. Weiss, *Genetic Discrimination: Perceptions of Consumers*, 274 SCIENCE 621, 622 (1996).

[33] *Id.*

[34] Ellen T. Matloff et al., *What Would You Do? Specialists' Perspectives on Cancer Genetic Testing, Prophylactic Surgery, and Insurance Discrimination*, 18 J. OF CLINICAL ONCOLOGY 2484, 2488 (2000).

[35] *Id.*

[36] Karen Pollitz et al., *Genetic Discrimination in Health Insurance: Current Legal Protections and Industry Practices*, 44 INQUIRY 350, 365 (2007).

[37] *Genetic Information in the Workplace*, *supra* note 19, at 7.

[38] GENETICS & PUB. POLICY CTR., PUBLIC AWARENESS AND ATTITUDES ABOUT REPRODUCTIVE GENETIC TECHNOLOGY (2004).

[39] GENETICS & PUB. POLICY CTR., REPRODUCTIVE GENETIC TESTING: WHAT AMERICA THINKS 42 (2004).

[40] *Id.*

and regulations to protect the privacy of individuals' genetic information, and eighty-five percent said that without amending current law, employers would use this information to discriminate among employees.[41]

Clearly, there was a need and public will for measures to be taken to protect the basic rights of every American. For life-saving scientific advances to continue and for the potential of genome technology to be fully realized, genetic testing had to be something commonplace rather than something feared. The promise of genomics is in jeopardy if our laws fail to adequately protect citizens from abuse and misuses of genetic information.

D. Legislative Precedent

Over the past 50 years, Congress enacted a number of civil rights statutes prohibiting discrimination based on race, color, religion, national origin, sex, disability, and age. These federal laws helped improve the lives of Americans by providing equal opportunities in education and employment. However, none of these statutes include language to directly address discrimination based on genetic information. For example, Title VII of the Civil Rights Act of 1964 makes it illegal for an employer, labor organization, employment agency or training program to "discriminate against any individual . . . because of such individual's race, color, religion, sex or national origin."[42] It makes no mention, however, of genetic information, or even any kind of health information.

In order to address this gap in protections against discrimination, a patchwork of state laws were implemented to address genetic information discrimination before GINA was enacted in 2008. In 1991, Wisconsin became the first state to pass a law prohibiting health insurers from using genetic information for making eligibility or risk classification decisions.[43] By 2008, more than 40 states restricted the use of genetic information by insurers, and more than 30 states prohibited genetic discrimination by employers.[44] However, state laws varied in their level of protection. New Jersey defined genetic information broadly, while other states, such as Florida and Arkansas, defined genetic information as only information obtained from genetic testing.[45]

By the mid-1990s, certain federal genetic discrimination protections were in place. The Americans with Disabilities Act of 1990 ("ADA") already provided some protections for genetic discrimination related to a disa-

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[41] COGENT RESEARCH, AMERICANS' ATTITUDES TOWARDS GENETIC DISCRIMINATION 8 (2006).

[42] Civil Rights Act of 1964, 42 U.S.C. § 2000e-2(a)(1) (2006).

[43] Susannah Baruch & Kathy Hudson, *Civilian and Military Genetics: Nondiscrimination Policy in a Post-GINA World*, 83 THE AM. J. OF HUMAN GENETICS 435, 437 (2008).

[44] *Id.*

[45] *Compare* N.J. STAT. ANN. § 17B:30-12(e)(2) (West 2009) *with* FLA. STAT. ANN. § 627.4301(1)(a) (West 2005) *and* ARK. CODE ANN. § 23-66-320(b)(3)(A) (2001).

bility.[46] However, individuals who carry genetic mutations but do not have a symptomatic genetic disorder were not explicitly covered. In 1995, the EEOC issued enforcement guidance, advising employers not to take action against healthy employees who carry genetic mutations that might predispose them for disease.[47] But a guidance measure is not legally binding, and does not guarantee protection from discrimination. In addition to these limitations, the ADA does not prohibit employer access to genetic information.[48]

In 1996, Congress passed the Health Insurance Portability and Accountability Act ("HIPAA"),[49] which included two provisions that restricted group health insurers' use of health-related information in making coverage decisions and setting premiums.[50] Genetic information may not be used for these purposes if it is maintained by a health provider or health plan covered by the act.[51] HIPAA also specifically stated that genetic information in the absence of a diagnosis cannot be considered a pre-existing condition.[52] While such protections were a step in the right direction, further clarification with respect to genetic information and genetic testing was needed. For example, HIPAA does not prohibit health insurance issuers from requesting genetic information from individuals already covered by a plan or using genetic information during the insurance underwriting process.[53] In addition, while HIPAA prohibits health insurers from charging higher premiums of an individual within a group plan based on genetic makeup, it allows insurers to charge the entire group a higher rate.[54] Finally, HIPAA failed to limit the disclosure of genetic information to insurers by outside parties.[55]

Congressional action was needed to create comprehensive legislation to address gaps at the state and federal level in order to ensure against the discrimination of individuals on the basis of genetic information. GINA was straightforward, commonsense, and necessary legislation to protect Americans from discrimination, yet over the years it ran into roadblock after roadblock.

II. GINA Legislative History

The legislative history of GINA can be divided into roughly four parts. 1) During the first few years after introducing the bill in the 104th Congress,

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[46] Americans with Disabilities Act of 1990, 42 U.S.C. § 12112 (2006).

[47] Equal Emp't Opportunity Comm'n, Compliance Manual, vol. 2, Section 902, Order 915.002, 902-45 (1995).

[48] Sarata & Williams, *supra* note 23, at 7.

[49] Pub. L. No. 104-191, 110 Stat. 1936.

[50] U.S. Dep't of Labor, Your Health Plan and HIPAA . . . Making the Law Work for You (Oct. 2009), *available at* http://www.dol.gov/ebsa/pdf/yhphipaa.pdf.

[51] 45 C.F.R § 160.103 (2011); 45 C.F.R § 164.501 (2011).

[52] Sarata & Williams, *supra* note 23, at 2.

[53] *Id.*

[54] *Id.* at 5.

[55] *Id.* at 23.

we focused on convincing members of Congress that legislation was a necessary step in assuring the American people that their private genetic information would not be used against them by insurance companies. 2) In the 106th Congress, a second title was added to the bill to protect individuals against genetic discrimination in the workplace. 3) Momentum for the bill vanished following the horrifying attacks of September 11, 2001 when Congress's attention focused on nothing but homeland security. 4) Finally, in the 110th Congress, the Democrats assumed control of both chambers of Congress, and GINA moved through the legislative process with the help of many of my colleagues in the House and Senate and the hard work and dedication of numerous stakeholders.

A. Part I: Tackling Health Insurance (1995–1999)

I introduced the first version of GINA in 1995, my interest piqued by a seminal journal article by Francis Collins and others about the ethical, legal and social implications of the Human Genome Project.[56] The intent of the bill was to alleviate fears on the part of the American public that genetic information could be used against them by health insurance companies.[57] This original bill addressed the problem by prohibiting insurance providers from denying or canceling health coverage, or varying premiums, terms or conditions on the basis of genetic information. In addition, it prohibited providers from requesting or requiring individuals to disclose genetic information, and included a measure to protect genetic privacy. At the time, only about 300 genetic tests were available, mostly for rare diseases or research purposes.[58] The healthcare research and policy communities called the legislation "forward looking."[59] Others called it "premature."[60]

By the end of the 104th Congress, GINA had garnered 76 bipartisan cosponsors among House members. That same Congress, Senator Olympia Snowe (R-Me.) introduced a companion bill in the Senate, and the Senate Committee on Health, Education, Labor and Pensions began to hold hearings on the public policy implications of genetic research.[61] Even though the bill did not pass the House or the Senate, the groundwork for GINA had been laid, and an encouraging level of interest had been displayed by members of Congress.

The legislation was reviewed and overhauled for reintroduction the following year. The passage of HIPAA in 1996 had placed in law the first

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[56] *See generally* Kathy L. Hudson et al., *Genetic Discrimination and Health Insurance: An Urgent Need for Reform* 270 SCIENCE 391 (1995).

[57] GENETICS & PUB. POLICY CTR., *supra* note 38, at 1, 10, 12–13.

[58] N. LEE RUCKER, AARP PUB. POLICY INST., FACT SHEET 156: THE GINA LAW: CONSUMER PROTECTION IN A NEW ERA OF GENETIC TESTING 3 (2009).

[59] Hudson, *supra* note 25, at 2661.

[60] Hudson, *supra* note 25, at 2661.

[61] *Genetic Information in the Workplace*, *supra* note 19.

explicit references to and protections for genetic information.[62] Given that some of the goals of the original version of GINA had been achieved through HIPAA, the bill was redrafted to conform to HIPAA's structures and address the gaps that remained. The bill was reintroduced on the first day of the new Congress, and I set to work collecting cosponsors as quickly as possible. By the middle of 1998, the legislation had the support of over 200 cosponsors, representing a near-majority of the House.

At that point, I filed a Motion to Discharge Committee (Petition No: 105-4),[63] also known as a discharge petition, which would have brought the bill directly to the floor of the House for consideration by the full body. This legislative maneuver had been used only very rarely in the past, but was being attempted more frequently, with at least eight discharge petitions filed that Congress. The discharge petition is, however, a challenge to obtain because it requires the signatures of a majority of Representatives, which means that some members of the majority party must sign the petition in express defiance of the wishes of their committee chairs and leadership. Our motion fell short of the 218 signatures required, and the Republican leadership of the committees of jurisdiction continued to refuse to allow its consideration.[64]

During the first few years, we engaged in a long-term education campaign to raise awareness among my colleagues. We sent out notices and letters, organized informational briefings, and shared news articles and scientific developments with members of Congress and their staffers. I spent a great deal of time convincing my fellow representatives that the legislation did not address cloning, which was problematic for many members of Congress on moral, ethical or religious grounds, particularly when discussing reproductive cloning (the asexual creation of a human being through cloning technology).[65] Some members of Congress did not understand the difference between cloning, stem cell research, and genetic information about health conditions. Educating non-experts on complex scientific concepts was a process that would take years.

B. Part II: Negotiating Employer Discrimination (1999–2001)

Much of the advocacy work by pro-GINA stakeholders over the years was centered upon extending GINA to cover employer discrimination. Republicans were reluctant to add an employer provision to GINA, arguing that genetic discrimination by employers was already covered by the ADA. It was not until the 106th Congress that a second title was incorporated into

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[62] SARATA & WILLIAMS, *supra* note 23, at 1–2.

[63] H.R. REP. NO. 110-28, pt. 1, at 23 (2007).

[64] *Id.*

[65] M. Asif Ismail, *In Congress, A Cloning Stalemate: Efforts to Ban Cloning Falter Over Scope of Proposed Prohibition*, THE CTR. FOR PUB. INTEGRITY (June 2, 2004, 12:00 AM), *available at* http://www.publicintegrity.org/2004/06/02/6427/congress-cloning-stalemate.

GINA to prohibit genetic discrimination by employers. The resulting bill (H.R. 2457) merged GINA, which covered only health insurance, with a separate, more recent piece of legislation that addressed genetic discrimination in employment, and enabled advocates to unify our work around a single, comprehensive bill.

Over the next several years we continued to build support among members in both the House and Senate as well as among stakeholders. In the 107th Congress, Senator Jeffords (I-Vt.) called a high profile hearing on Genetic Information in the Workplace. In 2000, under the guidance of Senator Jeffords, then Chair of the U.S. Senate Committee on Health, Education, Labor, and Pensions, the Senate adopted an amendment to the Labor, Health and Human Services Appropriations bill to establish safeguards within the insurance companies to protect an individual's genetic information.[66] The measure was later removed by the Conference Committee on that bill, but it indicated a victory for our educational campaign in that there was heightened interest in advancing non-discrimination legislation regarding health insurers.

Despite the support of over 500 organizations, a smaller but more powerful group opposed the bill. The Genetic Information Nondiscrimination in Employment ("GINE") Coalition, led by the U.S. Chamber of Commerce, represented a group of trade associations and professional organizations such as the Society for Human Resource Management, the National Association of Manufacturers ("NAM"), the HR Policy Association, and the College and University Professional Association for Human Resources. The GINE Coalition opposed GINA, arguing on several grounds that new federal legislation was not needed.[67]

One argument the GINE Coalition made time and time again was that existing federal laws already provided sufficient protections. The U.S. Chamber of Commerce testified before the House Committee on Education and the Workforce in 2004, arguing that state laws, the ADA, and HIPAA all alleviated the need for additional legislation. However, as previously mentioned, the patchwork of state laws varied in the level of protection against discrimination, the ADA did not guarantee full protections for employees, and HIPAA had significant limitations as well.

The GINE Coalition also made several arguments that the provisions in GINA would put an unreasonable burden on employers. There were concerns that employers would be targeted by frivolous and excessive lawsuits, either because the health benefits mandate in GINA would permit plaintiffs to sue an employer for offering benefits that do not cover treatment for a specific genetic condition, or because the definition of "family member" in

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[66] James M. Jeffords & Tom Daschle, *Political Issues in the Genome Era*, 291 SCIENCE 1249, 1250 (2001).

[67] Letter from the Genetic Info. Nondiscrimination in Emp't ("GINE") Coal. to Cong. Representatives (Jan. 29, 2007) (on file with author), *available at* http://www.uschamber.com/sites/default/files/issues/labor/files/ginacoalitionletteropposingh.r.493.pdf.

GINA was too expansive and would increase the likelihood of litigation.[68] In addition, there were concerns regarding the recordkeeping requirements in GINA.[69] Opponents argued that employers could face substantial damages for paperwork violations such as failing to properly distinguish genetic information from other health care information.[70] It was also argued that it would be too confusing for employers would be required to follow one set of rules for handling genetic information and a different set for other health care information.[71]

Year after year, my chief of staff sat around the table negotiating with staffers from House and Senate offices and stakeholders in support of and opposed to GINA, including the Genetic Alliance (a coalition of over 600 groups), the Chamber of Commerce, and insurance lobbyists. Every provision was debated and reworked. Every definition was deliberated and revised. As the years passed, GINA grew in length to reflect its growing complexity. I was frustrated by the loss of simplicity. The intention of this bill was so straightforward, but the special interests of the health insurance industry and the Chamber of Commerce demanded specifics and narrowing of the bill's language.

In 2000, a turning point in the battle came when President Clinton issued Executive Order 13145, To Prohibit Discrimination in Federal Employment Based on Genetic Information. This executive order explicitly prohibited discrimination on the basis of genetic information in all aspects of civilian federal government employment and limits federal departments and agencies' access to and use of genetic information.[72] The order protected 2.8 million federal employees and aimed to send a powerful message to the private sector on how to handle advances in genomics. President Clinton also stated that Congress should pass legislation to protect private employees from genetic discrimination.[73] His directive provided much-needed leverage and was crucial in moving the negotiations forward. Former Majority Leader Tom Daschle (D-S.D.) and Senator Ted Kennedy (D-Mass.) declared that when the Senate switched to Democratic control they would push GINA through in a matter of months. (They kept their promise, and GINA twice passed the Senate—unanimously—first in 2003 and again in 2005, but without Democratic control in the House the bill would not move further.)

On June 23, 2001, President George W. Bush announced in a radio broadcast that he would support a law that prevents insurance companies and

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[68] *Id.* at 1–2. GINA defines "family member" as any individual related by blood no matter how remote the relationship, and only covers genetic conditions for which information is scientifically proven to reveal patterns of inheritance. Genetic Information Nondscrimination Act, Pub. L. No. 110-233, 122 Stat. 881 (2008) (codified at 29 U.S.C.§ 1191b(d)(9)).

[69] Letter from the GINE Coal., *supra* note 67, at 2.

[70] *Id.* at 1.

[71] *Id.* at 2.

[72] Exec. Order No. 13,145, 3 C.F.R. 235 (2000).

[73] Remarks on Signing an Executive Order to Prohibit Discrimination in Federal Employment Based on Genetic Information, 36 WEEKLY COMP. PRES. DOCS. 241 (Feb. 8, 2000).

employers from using genetic information to deny medical coverage or turn down people for jobs.[74] In that address, President Bush declared that:

> Genetic discrimination is unfair to workers and their families. It is unjustified—among other reasons, because it involves little more than medical speculation. A genetic predisposition toward cancer or heart disease does not mean the condition will develop. To deny employment or insurance to a healthy person based only on a predisposition violates our country's belief in equal treatment and individual merit.[75]

This statement seemed to present a tantalizing opportunity to persuade the previously unreceptive Republican committee chairs and Congressional leadership to take up this issue. But this momentum would not last.

C. Part III: The Long Haul (2001–2006)

On September 11, 2001, America was devastated by four coordinated suicide attacks in New York City and Washington, D.C. Our world would never be the same. For the next two years, Congress worked primarily on legislation related to homeland security and all other issues, including GINA, fell by the wayside.

It was not until 2004 that I began to see interest for GINA begin to rebuild. My colleagues and I redoubled our efforts to press for the bill's passage. We had accrued over 200 letters of support from over 500 organizations representing a wide range of health care interests, including providers, consumers, and other advocates. Advocacy groups such as the Coalition for Genetic Fairness, the Personalized Medicine Coalition, the American Academy of Pediatrics, the American Heart Association, and industry leaders, such as Affymetrix, Genzyme and Millennium Pharmaceuticals, all supported GINA.

At this time, there was also growing support for GINA among the American people. In 2004, ninety-two percent of participants surveyed by the Genetics and Public Policy Center at Johns Hopkins University did not want employers to have access to their genetic information.[76] Eighty percent of those surveyed said their genetic information should be kept private from health insurers.[77]

During the 107th and 108th Congresses, the most meaningful negotiations with the opposition took place. It was determined that it would be unfair to insurance companies for penalties to be inconsistent with penalties

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[74] Presidential Radio Address to the Nation, 37 WEEKLY COMP. PRES. DOCS. 963 (June 23, 2001).

[75] *Id.*

[76] GENETICS AND PUB. POLICY CTR., *supra* note 2, at 2.

[77] GENETICS AND PUB. POLICY CTR., *supra* note 2, at 2.

already established by anti-discrimination statutes. Therefore, the penalties in GINA were made consistent with comparable provisions under the ADA and the Civil Rights Act of 1964. We also agreed to leave out life, long-term, and disability insurance, not because these kinds of insurance should be exempt from genetic non-discrimination laws, but because they relied upon a distinct set of determinants that warranted a separate conversation and stand-alone legislation. Each of those types of coverage require a time-limited substantial payout that could be tremendously variable depending upon an individual's medical risk. Therefore, having prior knowledge of one's risk for certain genetic disorders could influence people to purchase more coverage, and perhaps closer to their time of need, than they would otherwise. This situation could potentially skew the risk pool to the point that it could impact the viability of insurers. By contrast, health coverage tends to be used incrementally over long periods of time. Rather than attempting to address this disparate situation in one piece of legislation, it was agreed that GINA should limit its focus on discrimination by health insurers and employers, with the possibility for future legislation remaining open.

In the 108th Congress (2003–2004) we garnered 242 cosponsors on the House bill, which was referred to the House Committees on Education and the Workforce, Energy and Commerce, and Ways and Means. Then-Chairman John Boehner (R-Ohio) of the Education and Workforce Committee held a hearing on the implications of non-discrimination on workers and employers. However, he did not schedule any follow up action for the bill. Similarly, Chairman Joe Barton (R-Tex.) of the Energy and Commerce Committee blocked any action on GINA. The GINE Coalition played a powerful role in convincing the Republican leadership to block the bill.[78] As a result, GINA was not reported out of committee, and it was not voted upon by the House of Representatives.

Given these partisan challenges, during the 109th Congress, we tried a different approach. The House was Republican-controlled, so I stepped aside and let Congresswoman Judy Biggert (R-Ill.) introduce GINA in hopes that a Republican-led bill might move the legislative process forward. However, despite Congresswoman Biggert's efforts to leverage her relationship with the Speaker, the support of 244 bipartisan cosponsors, and an official Statement of Administration Policy ("SAP") in support of GINA,[79] as with previous Congresses, no action was taken.

D. Part IV: Passage of GINA (2007–2008)

The 110th Congress, beginning in 2007, marked the first time since the end of the 103rd Congress back in 1995 that the Democratic Party carried the majority in both the House and Senate. Congresswoman Nancy Pelosi

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[78] *See* Letter from GINE, *supra* note 67.

[79] 151 CONG. REC. S1481 (daily ed. Feb. 16, 2005) (Statement of Administration Policy).

(D-Cal.) made history by becoming the first female Speaker of the House, ushering in a new phase for the passage of GINA, and the promise of what would eventually become the most productive Congress since the 1960s. I again took the lead on GINA, reintroducing the bill on January 16, 2007 with my Republican colleague, Congresswoman Biggert. We garnered over 200 bipartisan cosponsors and finally, after all of our years of hard work and perseverance, the bill began to move in the House.

In January 2007, the House Subcommittee on Health, Employment, Labor and Pensions held a hearing on the bill. Congresswoman Biggert and I served as witnesses along with stakeholders on both sides of the issue. On February 14, 2007, the Committee on Education and Labor convened a markup of GINA and the Committee voted to report favorably on the bill by voice vote. Despite concerns about delivery of healthcare, worries about Title II information regulations, and fears that GINA would create confusion for the 43 States that already had laws prohibiting discrimination based on genetic information, in March 2007, GINA was reported out by the Committee on Ways and Means and the Committee on Energy and Commerce. After consideration by four committees in the House, in April of 2007—nearly twelve years after I initially introduced a genetics anti-discrimination bill—the House took its first vote on GINA. The vote was overwhelming—GINA passed 420 to 3. That same day, the President once again indicated his support for legislation.[80]

It took us another year filled with negotiations to get a vote in the Senate. Even though the Senate had passed GINA unanimously twice in previous Congresses, many in the Senate had the luxury of being able to vote knowing full well that this bill would not pass the House. Senator Coburn (R-Okla.) initially put a hold on GINA, blocking the bill from coming to the Senate floor for a vote. He wanted changes to the bill to address fears about exposing employers and insurance companies to lawsuits and objected to provisions that allowed discrimination based on genetic information from embryos and fetuses. During House Committee negotiations the inclusion of the phrase "born to" had also raised significant concern among many Republicans, as they feared it could be read to exclude genetic discrimination protections for children not yet born or embryos prepared for in vitro fertilization. Supporters of GINA, including members of both parties, agreed that the language as drafted already protected against these scenarios, and after some minor changes to the bill language, in early 2008, Senator Coburn released his hold, allowing the Senate to vote on GINA in April of 2008. GINA passed unanimously by a vote of 95-0. The Senate sent the slightly altered bill back to the House, where it again passed with overwhelming support. On May 21st, 2008, after over a decade of hard work and perseverance, I watched President Bush sign GINA into law.

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[80] 153 CONG. REC. H4098 (daily ed. Apr. 25, 2007) (Statement of Administration Policy).

III. GINA Provisions

The purpose of GINA is to protect individuals from discrimination by health insurers and employers on the basis of genetic information. These protections were established to allay individual's concerns about the potential for discrimination, and to encourage participation in genetic research, genetic testing, new technologies, and new therapies.

A. Title I

Title I of GINA contains the health insurance provisions, and applies to employer-sponsored group health plans, health insurance issuers in the group and individual markets, Medigap insurance, and state and local nonfederal governmental plans.[81] The HHS Standards for Privacy of Individually Identifiable Health Information (medical privacy regulations) already protect the use and disclosure of all individually identifiable health information, including genetic information.[82] However, a permitted "use" of health information under the privacy rules is insurance underwriting.[83] GINA expressly bans the use or disclosure of genetic information for the purposes of underwriting. Notably, GINA does not mandate coverage of any particular genetic test or treatment. It also does not prohibit medical underwriting based on current health status.

GINA amends the Employee Retirement Income Security Act of 1974 ("ERISA") to clarify that protected genetic information includes "any request for, or receipt of, genetic services, or participation in clinical research that includes genetic services, by such individual or any family member of such individual."[84] GINA prohibits a health insurance issuer from adjusting premiums or contributing amounts for a group on the basis of genetic information.[85] In addition, GINA amends the Public Health Service Act ("PHSA"), the Internal Revenue Code of 1986, and title XVIII of the Social Security Act, and generally uses the same mechanisms to enforce protections established under this legislation as apply to other violations of underlying statutes.[86] Furthermore, GINA makes it illegal for group health plans and health insurers to deny coverage to a healthy individual or charge him or her higher premiums based solely on a genetic predisposition to a specific disease.[87] Title I also covers family history data on genetic information, and

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[81] Genetic Information Nondiscrimination Act of 2008, P.L. 110-233, tit. I (codified at 29 U.S.C. § 1182).

[82] 45 C.F.R. § 160.103 (2011); 45 C.F.R. § 164.502 (2009).

[83] 45 C.F.R. §§ 164.501, 164.502(a)(1)(ii) (2009).

[84] Genetic Information Nondiscrimination Act § 101(d) (codified at 29 U.S.C. § 1191b(d)).

[85] § 101(a)(2) (codified at 29 U.S.C. § 1182).

[86] §§ 102; 103; 104.

[87] §§ 101(b); 102(a)(2); 102(b)(1)(B).

prohibits an insurer from requesting or requiring that a person undergo a genetic test.

B. Title II

Title II of GINA contains the employment provisions, which prohibit employment discrimination on the basis of genetic information, such as hiring, firing, job assignments, and promotions.[88] The bill extends to employers, unions, employment agencies, and labor-management training programs.[89] In addition, GINA safeguards the confidentiality of genetic information in the employment setting. It prohibits employers with greater than fifteen employees from requesting, requiring, or purchasing genetic information about an individual or their family members.[90]

Employers, labor organizations, employment agencies, and joint labor-management committees generally are prohibited from requesting, requiring, or purchasing genetic information about an employee or family member, except for a few legitimate reasons. For example, the purchase of commercially and publicly available documents or inadvertently requesting or requiring family medical history would not violate this title.[91] Under each of the exceptions, the genetic information still could not be used or disclosed.[92] Regardless of when genetic information was obtained or collected—before or after law enactment—GINA restricts the use of this information.

C. Enforcement

GINA is enforced by the Department of Health and Human Services ("HHS"), the Department of Labor, the Department of the Treasury, and the Equal Employment Opportunity Commission ("EEOC"). As written, GINA directed that Title I (health insurance) take effect in May 2009 and Title II (employment) take effect in November 2009.[93] EEOC issued final regulations for Title II in November 2010, which were effective January 10, 2011. However, at the time of this publication, the regulations for Title I remain in "interim final" stage, meaning that finalization for this regulation remains pending. We are still awaiting final review by HHS and the Office of Management and Budget.

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[88] Tit. II, § 202(a) (codified at 42 U.S.C. 2000ff-1).
[89] § 205(a) (codified at 42 U.S.C. § 2000ff-4).
[90] § 202(b) (to be codified at 42 U.S.C. § 2000ff-1).
[91] §§ 202(b)(1); 202(b)(4).
[92] § 202(c).
[93] §§ 101(f); 102(d); 104(c); 213.

D. Interaction with State Laws

GINA sets a nationwide level of protection, but does not preempt state laws that provide even broader safeguards. States not in compliance will need to revise their laws to meet the standard provided by GINA. Penalties for violations include corrective action and monetary penalties.

E. Interaction with the ACA

Finding a way to reconcile the need for doctors to treat patients with the necessity of individual privacy protections was one area of vigorous debate during the years of GINA negotiation. After extensive discussion over a period of months, the sponsors of GINA and advocates agreed that the privacy protections of GINA would only apply prior to the medical diagnosis of a disease, but not afterwards. The rationale behind this decision was threefold. First, it was generally agreed that discrimination prior to diagnosis was particularly egregious, since genetic information was of very limited utility in determining whether a specific individual might actually develop a condition for which he or she had a genetic predisposition. Individuals should be encouraged to obtain this predictive information and act upon it to improve their health without fear of discrimination. Second, extending the reach of the legislation beyond diagnosis presented the conundrum that individuals with the same disease or disorder might have different levels of protection depending upon whether they had a genetic or acquired version of the condition. For example, a child born with epilepsy could expect to be protected under GINA, while a child who developed epilepsy after a brain injury could not. Third, there was great concern that protecting the privacy of genetic information after diagnosis might interfere with the ability to treat patients by impeding the flow of medical information among health care professionals. All parties agreed that it was vitally important to allow all treating health care providers to share genetic information in order to take advantage of personalized medicine and facilitate the best and most appropriate treatment. The combination of these three issues led us to craft GINA to protect the privacy of genetic information before, but not after, diagnosis. We knew that this left a potential gap, because at the time insurance companies could deny individuals coverage based on a pre-existing condition; therefore, if a genetic disease was already diagnosed before an individual sought coverage, their rates could indeed be determined based on such factors.

Two years after the passage of GINA, Congress passed the Patient Protection and Affordable Care Act ("ACA"), a comprehensive health care legislation intended to, among other things, prohibit the use of pre-existing conditions by the private health insurance market in making decisions about

coverage.[94] This addressed the gap in coverage created when the line for GINA's protections was drawn at diagnosis of disease, which left the determination of a pre-existing condition open to interpretation, and affords even greater protections to the American consumer. While the two laws have overlapping provisions, they each serve complementary purposes. ACA prohibits denial of healthcare coverage based on genetic information, but GINA is significantly more stringent. ACA provisions on genetic information apply only to premium rates, while GINA provisions apply to premiums as well as contribution amounts. Specifically, GINA prohibits insurers from requesting, requiring, or purchasing genetic information for the purposes of underwriting or using genetic information to set premium rates and contribution amounts.

IV. Limitations of GINA

Critics of GINA have argued that its language is too narrow in scope. GINA does not protect against genetic discrimination in life, long-term care, or disability insurance or discrimination by creditors. As discussed previously, these limitations were a strategic decision to recognize distinct markets, social purposes, and bodies of law governing each type of insurance. I would argue that GINA remains an important step towards freedom from insidious discrimination, but it is by no means the end point. Just as access to all civil rights developed in stages, a first step was taken with the passage of GINA, but it was only the first step. Clearly more work is needed to protect the American people.

A. GINA and the Military

One glaring inconsistency with the intent of the legislation is that GINA does not apply to members of the U.S. Armed Forces, veterans obtaining healthcare through the Department of Veterans Affairs, or the Indian Health Service. This came about because the laws amended by GINA—ERISA, PHSA, HIPAA, and the Internal Revenue Code do not apply to these groups and programs. This was not a consequence of the legislation of which I was aware at the time of its drafting and passing. Our intention was not to leave any one out.

The Department of Defense ("DoD") collects genetic information from service members for multiple purposes. For example, all service members are required to provide a DNA sample for the purposes of identifying their remains should they fall in battle.[95] As of 2002, the Armed Forces Reposi-

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[94] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (codified in scattered sections of the U.S.C.) (2010).

[95] Notice to Alter a System of Records, Privacy Act of 1974; System of Records, Department of Defense, 62 Fed. Reg. 51,835 (Oct. 3, 1997).

tory of Specimen Samples for the Identification of Remains contained samples from 3.2 million service members.[96] The 2003 National Defense Authorization Act added a provision to allow DNA samples to also be used for limited law-enforcement purposes.[97] Since that time, there has been some discussion as to whether or not the repository should be used for additional purposes, such as biomedical research.[98] Such discussions do beg the question of whether or not the DoD is doing enough to protect the privacy of service members.

Up until 2008, DoD medical discharge and disability benefits for any injury or disease acquired during the course of active duty excluded congenital and hereditary conditions.[99] In other words, service members who developed a disease due to a genetic predisposition, as defined by the armed forces, were denied benefits.

Following the passage of GINA and in combination with shifting attitudes and better understanding of genetic information, DoD has begun to address some of the disparities between civilian and military policy. New policies addressing genetically-linked disabilities have helped to improve healthcare for service members. The National Defense Authorization Act of 2008 ("NDAA") was changed to include a new DoD Instruction on "Hereditary and/or Genetic Diseases," which states:

> Hereditary or genetic disease shall be evaluated to determine whether compelling evidence or medical judgment establishes that the disability was incurred prior to entry on active duty. However, even if the conclusion is that the disability was incurred prior to entry on active duty, any aggravation of that disease, incurred while the member is entitled to basic pay, beyond that determined to be due to natural progression shall be determined to be service aggravated.[100]

As with many advances in medicine and technology, the military is on the cutting edge of developing personalized medicine, which I believe holds the greatest promise in the area of genomics.[101] It was for the development of this type of advanced treatment—knowing which medications are most likely to successfully treat a specific individual's disease—that the protections offered by GINA were necessary. I have had multiple conversations with members of the Air Force's team dedicated to expanding personalized medicine—including the Surgeon General of the Air Force—and am confi-

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[96] Patricia A. Ham, *An Army of Suspects: The History and Constitutionality of the U.S. Military's DNA Repository and its Access for Law Enforcement Purposes,* 2003 ARMY LAW. 1.

[97] 10 U.S.C. § 1565a (2006).

[98] Baruch, *supra* note 43, at 440–1.

[99] U.S. Dep't of Def. Instruction 1332.38 (E.3.P.4.5.2.2) (2005).

[100] U.S. Dep't of Def., DoD Directive Type Memo Implementing 2008 NDAA; revised DoD Instruction E3.P4.5.2.2. on "Hereditary and/or Genetic Diseases" (2008).

[101] Bill Frist, *Personalized Medicine*, THE HILL'S CONGRESS BLOG (July 10, 2012, 7:49 PM), http://thehill.com/blogs/congress-blog/healthcare/237155.

dent that the policies they have developed sufficiently offer the same protections from discrimination to members of the military that GINA provides other Americans. I continue to monitor the situation, however, and consider whether legislation to codify such protections is necessary to assure that the same protections are offered across all branches of the military.

V. Current Challenges

In addition to considering the need for and feasibility of standalone legislation to address the gaps identified previously in this article (life, long term care, disability insurance, etc.), there are three major challenges that I would like to address following the passage of GINA. The first is how to assess the impact of GINA with regard to improving non-discrimination as well as research participation. A second challenge is how to address the lack of awareness of GINA's protections on the part of the average American—including physicians and other medical professionals. Finally, we will have to address the challenge of negotiating how electronic records can best be used to assist medical practitioners without sacrificing the genetic privacy of their patients.

A. Impact Assessment

The intent of GINA was two-fold: to prohibit discrimination based on genetic information and to encourage genetic testing and participation in genetic research studies. In passing legislation as a largely preventive measure, the impact of GINA on genetic discrimination was obscured by its own success. At the time of enactment, studies documenting genetic discrimination had not been implemented on a systemic level. There also is no baseline data indicating the rates at which individuals declined to participate in genetic testing or clinical trials due to the fear of discrimination, so we cannot report on a change in this behavior related to the passage of GINA. Under these circumstances, it is extremely difficult to determine whether GINA has reduced or prevented cases of genetic discrimination.

We do, however, have enforcement data from the EEOC. For 2010–2011, the EEOC found reasonable cause to believe genetic discrimination has occurred in 143 cases, and a half million dollars has been awarded in damages in 2011–2012.[102] In my opinion, these statistics are certainly evidence of success of the law.

Furthermore, we know that practice has changed for investigators performing research studies that include genetic testing. The Department of Health and Human Services put out GINA guidance for investigators and

[102] *Genetic Information Non-Discrimination Act Charges FY2010–2011*, U.S. Equal Emp't Opportunity Comm'n, http://www.eeoc.gov/eeoc/statistics/enforcement/genetic.cfm (last visited Oct. 6, 2012).

Institutional Review Boards in 2009[103] that suggests including the following information in informed consent agreements that participants read and sign prior to enrolling in research studies:

> A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
> • Health insurance companies and group health plans may not request your genetic information that we get from this research.
> • Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
> • Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
>
> All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.
> Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.[104]

Having this knowledge prior to participating in research should assuage many of the fears that previously prevented people from participating in research. I believe that we can point to the rapid advancement in personalized medicine and the myriad other advances in genetics and genomics as evidence that sufficient participation is taking place, just as we hoped to foster by passing this bill.

B. Education

Despite the fact that Congress passed GINA in 2008, a nationally representative survey from 2011 indicated that fewer than one in five Americans (16%) are aware this law exists.[105] Coupled with the observation that Americans are increasingly concerned about how their genetic information is

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[103] *See generally* U.S. Dep't of Health and Human Servs. Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (2009), *available at* http://www.hhs.gov/ohrp/policy/gina.pdf.

[104] *Id.* at 6.

[105] Press Release, Cogent Research, Americans' Concern about the Privacy of Their Genetic Information Reaches New High (Jan. 10, 2011) (on file with author).

stored and accessed,[106] this would indicate that lack of understanding is not due to lack of interest. Surprisingly, even among physicians, a staggering eighty-one percent are not familiar with GINA protections.[107]

The good news is that more than half of Americans would be interested in using their genetic information for the purpose of understanding and optimizing their health.[108] Measures must be taken to educate and inform the American people, physicians, researchers, insurers, employers, and all other stakeholders on the benefits and coverage of GINA. Each of these groups will have different needs and interests in GINA protections, but increased awareness will undoubtedly benefit all parties involved.

C. Data Sharing and Genetic Privacy

The ACA has already set into motion the shift by the healthcare community to Electronic Health Records ("EHR") adoption. Information technology holds great promise in improving the sharing of health data across the healthcare system, improving healthcare quality and reducing unnecessary costs. However, with this shift comes a number of ethical questions regarding how information should be shared with health insurance companies and employers. Concerns have also been raised about privacy protections. Data in digital form is far easier to obtain illegally or without a patient's knowledge than data in paper form. Although genetic information could be redacted from medical records when transmitted to a third party, current software design does not practically accommodate GINA provisions. Balancing health privacy with quality improvement and clinical effectiveness will have to be addressed more broadly as reliance on EHRs continues to grow.

The good news is that progress is being made on a state level. In 2011, the California Genetic Information Nondiscrimination Act ("CalGINA") went into effect.[109] CalGINA expands upon GINA protections to include housing, mortgage lending, education, and public accommodation. The law also extends nondiscrimination coverage to include employers with five or more employees. I continue to consider opportunities to address the needs for such coverage on a federal level.

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[106] *See generally* AMANDA K. SARATA, CONG. RESEARCH SERV., RL34376, GENETIC EXCEPTIONALISM: GENETIC INFORMATION AND PUBLIC POLICY (2011).

[107] Press Release, Cogent, *supra* note 105.

[108] Press Release, Cogent, *supra* note 105.

[109] Jennifer Wagner, *A New Law to Raise GINA's Floor in California*, GENOMICS LAW REPORT (Dec. 7, 2011), http://www.genomicslawreport.com/index.php/tag/calgina/.

VI. The Post-Genomic Era

A. Direct-to-Consumer Tests

Additional challenges, some that we cannot foresee at this time, are likely to develop as the rapid pace of medical advancement continues to barrel forward. For example, in July of 2012, a genetic test maker, 23andMe, submitted an initial batch of seven health-related direct-to-consumer genetic tests for FDA approval.[110] The company plans to submit an additional 100 tests over the next year. The FDA already regulates a number of genetic tests administered by healthcare providers, such as those administered to pregnant women to test for cystic fibrosis in the developing fetus. However, despite a Government Accountability Office ("GAO") report concluding that direct-to-consumer tests are "misleading, and of little or no practical use,"[111] the FDA has yet to promulgate regulatory guidance regarding them.

A recent report indicated that the U.S. represents the largest market for direct-to-consumer genetic tests.[112] Given that these tests lack the involvement of a medical practitioner, as well as the lack of a trained genetic counselor to properly interpret the results of such tests, clear regulatory measures should be taken to protect consumers from deceptive marketing and abuse of genetic privacy.[113] Direct-to-consumer tests are already regulated in countries such as Germany and South Korea, while countries such as the U.K. and Japan have a self-regulated industry.[114] At this time I am considering appropriate legislative responses to the development of direct-to-consumer genetic testing to ensure that consumers receive accurate, appropriate information and clear guidance in the proper interpretation of that information, even when they receive it in the privacy of their own home.

B. Genes and the Environment

Genes are not the only factor in determining our physiological health. Researchers have long recognized the influence of the environment on development and human health. In fact, the separation between genetic and environmental influence is rarely clear cut. Just as it is wrong to discriminate

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[110] *23andMe Personalized DNA Test Seeks FDA Approval*, CBS News (July 31, 2012), http://www.cbsnews.com/8301-504763_162-57483267-10391704/23andme-personalized-dna-test-seeks-fda-approval/.

[111] U.S. Gov't Accountability Office, GAO-10-847T, Direct-To-Consumer Genetic Tests: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices (2010).

[112] Press Release, Global Industry Analysts, Inc., Future of Direct-to-Consumer (DTC) Genetic Testing Market Remains Fraught with Challenges (Aug. 8, 2012) (on file with author).

[113] U.S. Gov't Accountability Office, *supra* note 111.

[114] Press Release, Global Industry Analysts, Inc., *supra* note 112.

against an individual based on their genetic makeup, it is also wrong to discriminate based on environmental factors outside of our control.

C. Personalized Medicine

As of 2012, more than 2,500 genetic tests for diseases exist.[115] While few cures are available for genetic disorders, genetic tests provide doctors and patients with valuable information about disease risk and can help guide preventative care measures. For example, a blood test for BRCA1 and BRCA2 gene mutations can indicate whether or not a woman is at higher risk of developing breast and ovarian cancer.[116] Armed with such information, a woman can choose to reduce her cancer risk by taking risk-lowering drugs, such as tamoxifen or raloxifene, or opt for prophylactic surgery.

Personalized medicine is poised to transform the future of healthcare. Along with great advances in biomedical research come new diagnostic tests and drug therapies that can be tailored to suit patient needs. For example, researchers and clinicians have shown that thirty percent of breast cancer patients have a specific form of the disease that is not responsive to standard therapy.[117] This type of cancer can be detected on a genetic level and patients can then be treated with a specific drug (Herceptin) effective at treating their disease.[118] There is also a molecular diagnostic test to help healthcare providers determine which patients will benefit from the drug, Selzentry, which targets a specific type of HIV.[119] Clinicians can now recommend appropriate dosage of drugs like Coumadin, which is used to prevent blood clots, based on a patient's genetic makeup.[120] Scientists are also exploring the medical applications of nanotechnology—technology at the atomic and molecular scale. Such advances have the potential to deliver drugs to specific places in the body, targeting treatment down to the cellular level.[121] Nanotechnology could be used to target tumors within the body or to be specifically designed for a particular individual.[122] These and other advances are just the beginning for personalized medicine.

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[115] *GeneTests: Growth of Laboratory Directory*, NAT'L CTR. FOR BIOTECH. INFO., http://www.ncbi.nlm.nih.gov/projects/GeneTests/static/whatsnew/labdirgrowth.shtml (last visited Oct. 6, 2012).

[116] *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT'L CANCER INST. FACT SHEET (May 29, 2009), http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA.

[117] BREAST CANCER FACTS AND FIGURES 2011–2012, AMERICAN CANCER SOCIETY (2011), *available at* http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-030975.pdf.

[118] Personalized Med. Coal., *The Case for Personalized Medicine*, THE AGE OF PERSONALIZED MEDICINE (May 2009), http://www.ageofpersonalizedmedicine.org/objects/pdfs/TheCaseforPersonalizedMedicine.pdf.

[119] *Id.*

[120] *Id.*

[121] U.S. DEPT OF HEALTH AND HUMAN SERVS., CANCER NANOTECHNOLOGY: GOING SMALL FOR BIG ADVANCES (2004).

[122] *Id.*

Although "designer drugs" hold much promise for healthcare, these advances also carry significant challenges and costs. Already drug companies have little financial incentive to develop drugs for rare diseases. Genetic profiling for individualized drug treatments has the potential to fragment the market and reduce the financial incentive for pharmaceutical and biotech companies to research and develop personalized medicines. Lawmakers and government agencies will have to address such challenges in order to encourage innovation and continued biomedical progress.

VII. Conclusion

The sequencing of the human genome held great promise for human health, but at the same time held great potential for stigmatization and discrimination. As Senator Jeffords and Senator Daschle once rightly stated, "Without adequate safeguards, the genetic revolution could mean one step forward for science and two steps backwards for civil rights."[123] Indeed, GINA has done more than stamp out a new form of discrimination. It has helped our country become a leader in the field of genomic research, and helped us realize the tremendous potential of scientific advancement without jeopardizing our fundamental right to privacy.

When GINA passed in 2008, the late Senator Kennedy (D-Mass.) declared it the "first civil rights bill of the new century."[124] This momentous event was the culmination of a dedicated systematic and bipartisan effort. Members on both sides of the aisle were committed to moving this bill forward. Senator Kennedy, Senator Snowe (R-Me.), and Senator Enzi (R-Wyo.) worked with Senator Reid (D-Nev.) and Senate leadership. Senator Gregg (R-N.H.), Senator Dodd (D-Conn.), and Senator Harkin (D-Iowa) also made important contributions. In addition, I could not have succeeded without the strong support of my House colleagues, particularly Speaker Pelosi (D-Cal.), Congresswoman Biggert (R-Ill.), Education and Labor Chairman Miller (D-Cal.), Ways and Means Chairman Rangel (D-N.Y.), and Energy and Commerce Chairman Dingell (D-Mich.). I will forever be grateful to these individuals and their dedicated staff for taking on this battle with me.

In this business, you're never defeated until you give up—and I never give up. GINA took thirteen long years to pass the House and Senate and get signed into law. I consider it one of my greatest achievements as a member of Congress. I am proud of the potential it offers to advance medical research and treatment by freeing people from the fear of losing their job or health insurance based on genetic information. As with all incremental advances in civil rights, the fight must continue and more must be done. I look forward to the continued challenge of protecting American citizens.

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[123] Jeffords & Daschle, *supra* note 66, at 1249.

[124] Press Release, U.S. Senate Comm. on Health, Educ., Labor, & Pensions, *supra* note 1.