



Genetic discrimination: emerging ethical challenges in the context of advancing technology

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ABSTRACT

Genetic testing is becoming more widespread, and its capabilities and predictive power are growing. In this paper, we evaluate the ethical justifications for and strength of the US legal framework that aims to protect patients, research participants, and consumers from genetic discrimination in employment and health insurance settings in the context of advancing genetic technology. The Genetic Information Nondiscrimination Act (GINA) and other laws prohibit genetic and other health-related discrimination in the United States, but these laws have significant limitations, and some provisions are under threat. If accuracy and predictive power increase, specific instances of use of genetic information by employers may indeed become ethically justifiable; however, any changes to laws would need to be adopted cautiously, if at all, given that people have consented to genetic testing with the expectation that there would be no genetic discrimination in employment or health insurance settings. However, if our society values

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access to healthcare for both the healthy and the sick, we should uphold strict and broad prohibitions against genetic and health-related discrimination in the context of health insurance, including employer-based health insurance. This is an extremely important but often overlooked consideration in the current US debate on healthcare.

KEYWORDS: genetic discrimination, affordable care act, wellness program, pre-existing conditions, genetic information nondiscrimination act, precision medicine

INTRODUCTION

The international focus on and investment in genetic research will undoubtedly increase the ability to use genetic testing to predict many different individual characteristics and phenotypes, including the propensity for disease. According to the US National Institutes of Health (NIH), precision medicine is ‘an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.’¹ Many rare diseases are caused by a single gene defect. More common diseases such as diabetes and heart disease are polygenic and complex in nature, but scientists are identifying genetic factors that predict the risks of these diseases with greater precision and accuracy.² Other genetic research is aimed at strengthening the predictive power of genome-wide polygenic scores for specific measures of intelligence (and/or educational attainment)³ and athleticism.⁴ Although the accuracy and predictive power of polygenic risk scores still need improvement,⁵ it’s clear that many scientists are working to address this challenge.⁶ Regardless of whether selecting embryos for higher IQ is in the realm of possibility,⁷ genetic testing is enabling increasingly accurate predictions about human characteristics.

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- 1 National Institutes of Health, WHAT IS PRECISION MEDICINE? (2019), <https://ghr.nlm.nih.gov/primer/precisionmedicine/definition> (last visited Apr. 26, 2019).
 - 2 Amit V. Khera et al., *Genome-Wide Polygenic Scores for Common Diseases Identify Individuals with Risk Equivalent to Monogenic Mutations*, 50 NAT. GENET. 1219–1224 (2018), <http://www.ncbi.nlm.nih.gov/pubmed/30104762> (last visited Apr. 26, 2019); Michael Inouye et al., *Genomic Risk Prediction of Coronary Artery Disease in 480,000 Adults: Implications for Primary Prevention*, 72 J. AM. COLL. CARDIOL. 1883–1893 (2018), <http://www.ncbi.nlm.nih.gov/pubmed/30309464> (last visited Apr. 26, 2019).
 - 3 Robert Plomin & Sophie von Stumm, *The New Genetics of Intelligence*, 19 NAT. REV. GENET. 148–159 (2018), <http://www.ncbi.nlm.nih.gov/pubmed/29335645> (last visited Apr. 26, 2019); James J. Lee et al., *Gene Discovery and Polygenic Prediction from a Genome-Wide Association Study of Educational Attainment in 1.1 Million Individuals*, 50 NAT. GENET. 1112–1121 (2018), <http://www.ncbi.nlm.nih.gov/pubmed/30038396> (last visited Aug. 5, 2019).
 - 4 Yannis P. Pitsiladis et al., *Athlome Project Consortium: A Concerted Effort to Discover Genomic and Other “Omic” Markers of Athletic Performance*, 48 PHYSIOL. GENOMICS 183–190 (2016), <http://www.ncbi.nlm.nih.gov/pubmed/26715623> (last visited Apr. 26, 2019).
 - 5 Nicholas J. Wald & Robert Old, *The Illusion of Polygenic Disease Risk Prediction*, 21 GENET. MED. 1705–1707 (2019), <http://www.nature.com/articles/s41436-018-0418-5> (last visited Aug. 7, 2019).
 - 6 Nina J. Mars et al., *Polygenic and Clinical Risk Scores and Their Impact on Age at Onset of Cardiometabolic Diseases and Common Cancers*, BIORxiv 727057 (2019), <https://www.biorxiv.org/content/10.1101/727057v1> (last visited Aug. 7, 2019).
 - 7 Erik Parens, Paul S. Appelbaum & Wendy Chung, *Embryo Editing for Higher IQ is a Fantasy. Embryo Profiling for It Is Almost Here*, STAT NEWS, February 12, 2019, <https://www.statnews.com/2019/02/12/embryo-profiling-iq-almost-here/> (last visited November 18, 2019).

The Genetic Information Nondiscrimination Act (GINA) was enacted in 2008. In large part, the law was intended to allow patients to take advantage of genetic testing in clinical and research settings without fearing genetic discrimination. With knowledge about genotype/phenotype associations continuing to grow, it is worth reexamining the ethical justifications for prohibitions against genetic discrimination in employment and health insurance settings. Are our laws and policies sufficient, or will they need to evolve? With increasing accuracy of genetic testing, would it ever be appropriate to use genetic information to discriminate against or classify individuals in employment or health insurance settings? Our analysis must acknowledge that GINA has created an ethical obligation in its own right: Consumers, patients, and research participants have consented to genetic testing with the expectation that the results cannot be used in employment or health insurance settings.

We divide this paper into three parts. In Part I, we analyze ethical issues related to the use of genetic information by employers and health insurers. We also discuss how these two spheres overlap since many employers provide health insurance for employees. In Part II, we outline the central policies that collectively prohibit discrimination based on genetic information in the United States in employment and insurance settings and discuss the limitations of these protections. We discuss how laws that prohibit employment and health insurance discrimination based on health status are also important in the context of genetic conditions, when and if genetic disease becomes symptomatic. In Part III, we consider current and future challenges to the legal framework that prohibits genetic discrimination in employment and health insurance settings and make recommendations based on our ethical analysis. In the future, employers might justifiably argue that genetic information is relevant in specific employment decisions, and carveouts to GINA may indeed be warranted in narrow circumstances. However, if our society values equal access to healthcare, we must preserve broad and strict prohibitions against genetic and other health status discrimination in health insurance settings. The US health insurance system, which relies on for-profit insurers as well as employers, may become increasingly ethically problematic over time, if our predictive capabilities increase and insurance providers push back against protections in GINA and the Affordable Care Act (ACA).

PART I. GENETIC DISCRIMINATION: WHY AND WHY NOT

There is rationale for employers and health insurance providers to use genetic information about potential and/or current employees and insureds, but as the enactment of GINA demonstrates, there are many reasons to prohibit genetic discrimination in these settings (Tables 1 and 2). Notably, some of the ethical concerns relating to genetic discrimination differ in these two contexts. Yet these spheres do intersect, as many US citizens acquire health insurance through employers.

Employment Settings

Many factors—including accuracy of the information, relevance, uncertainty, control, and contractual expectations—influence whether it is fair to use genetic information in employment settings (Table 1). Yet some of the reasons to disallow genetic discrimination in employment settings, such as lack of control over genotype and the predictive/probabilistic nature of the information, are also true of other factors

Table 1. Considerations for use of genetic information in employment settings

	Reasons to disallow	Reasons to allow
Accuracy	Genetic tests do not accurately predict polygenic traits, due to complexity and influence of environment (nurture)	Genetic testing provides increasingly accurate risk prediction for traits; as an ‘objective’ measure, may contribute to fairness
Relevance	Prediction of future characteristics not relevant to current ability to do job	Some characteristics that can be predicted by genetic testing relevant to ability to do job (present or future); may even promote the health or safety of the employee or others; may allow genotype-specific accommodations
Uncertainty	Prediction of future abilities not diagnostic/deterministic; at best, can only provide probabilities	Other mechanisms to evaluate employees are also predictive/probabilistic: interviews, tests, etc.
Control	Employees do not have control over their genotype	Employees do not have full control over other qualities that are used to make employment decisions (e.g., education; social networks)
Contractual expectations	Consumers/research participants/patients have consented to testing with expectation that results cannot be used in employment settings	Laws/policies can evolve over time

that are used for employment decisions. Therefore, aside from the contractual expectations established by GINA, it seems that the most important ethical concerns regarding genetic discrimination in employment settings are accuracy and relevance of the information (Table 1). At least theoretically, some characteristics that can or will be predicted by genetic testing seem relevant to an employee’s ability to do certain jobs well or safely, either in the present or future. Since genetic factors influence individual traits, they almost certainly bear on employee characteristics. Employers may want to use genetic information to select, advance, not advance, or terminate employees based on predictions of traits, such as intelligence, athleticism, or empathy, among other phenotypes influenced by genetic factors. For example, sports teams have expressed interest in using genetic information to understand players’ unique abilities.⁸ There is some evidence that certain genetic variants are correlated with world-class athletic performance.⁹ Conversely, there are known genetic variants that raise an individual’s

8 Carina Dennis, *Rugby Team Converts to Give Gene Tests a Try*, 434 NATURE 260–261 (2005), <http://dx.doi.org/10.1038/434260a>.

9 Nan Yang et al., *ACTN3 Genotype Is Associated with Human Elite Athletic Performance*, 73 AM. J. HUM. GENET. 627–631 (2003), <https://www.sciencedirect.com/science/article/pii/S0002929707620242> (last visited Aug. 5, 2019); Jan Weyerstraß et al., *Nine Genetic Polymorphisms Associated with Power Athlete Status—*

Table 2. Considerations for use of genetic information in health insurance settings

	Reasons to disallow	Reasons to allow
Accuracy	Genetic tests do not accurately predict polygenic traits, due to complexity and influence of environment (nurture)	Genetic testing provides increasingly accurate risk prediction for traits; as an 'objective' measure, may contribute to fairness
Relevance		Disease prediction is relevant to likelihood of future use of healthcare services/products
Uncertainty	Prediction of future health not diagnostic/deterministic; at best, can only provide probabilities	Other mechanisms of predicting health are also probabilistic (age, gender, smoking status, occupation)
Control	People do not have control over their genotype	People do not have full control over other predictors of health (age, gender, etc.)
Political philosophy	Solidarity/community; purpose of health insurance is to spread risk across many so that most vulnerable are not overly burdened	Capitalism and free markets; for-profit insurance companies should not be forced to take on customers for whom costs will greatly exceed revenues
Adverse selection	No one is genetically 'perfect'/we all have variants that may be detrimental and/or beneficial	Those who have genetic predisposition to disease will be more likely to purchase health insurance
Contractual expectations	Consumers/research participants/patients have consented to testing with expectation that results cannot be used in health insurance settings	Laws/policies can evolve over time

risk of cardiac arrest, particularly during exercise.¹⁰ Employers of bus drivers or pilots may have a legitimate interest in genetic factors that would, hypothetically, significantly increase the chance of suffering an epileptic attack.¹¹ The US military, which is exempt

A Meta-Analysis, 21 J. SCI. MED. SPORT 213–220 (2018), <http://www.ncbi.nlm.nih.gov/pubmed/28666769> (last visited Aug. 5, 2019).

10 Allison L. Cirino & Carolyn Y. Ho, *Genetic Testing for Inherited Heart Disease*, 128 CIRCULATION e4–8 (2013), <https://www.ncbi.nlm.nih.gov/pubmed/23817488>; A. Zorzi, A. Pelliccia & D. Corrado, *Inherited Cardiomyopathies and Sports Participation*, 26 NETH HEART. J. 154–165 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5818378/>; Rajat Deo & Christine M. Albert, *Epidemiology and Genetics of Sudden Cardiac Death*, 125 CIRCULATION 620–637 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3399522/>.

11 Noah Levin, *A Defense of Genetic Discrimination*, 43 HASTINGS CENT. REP. 33–42 (2013), <http://www.ncbi.nlm.nih.gov/pubmed/23842922>.

from coverage by GINA, routinely screens service personnel for genetic conditions such as sickle cell trait and glucose-6-phosphate dehydrogenase (G6PD) deficiency and will likely leverage genomic technologies to support its mission.¹²

If relevance of genetic information can be granted in at least some specific situations, then accuracy of the information remains as the largest ethical concern (Table 1). Some believe that the complexity of genetics will always limit accurate prediction of complex traits like intelligence or athletic ability. Thus far, our understanding of the extent to which genetics versus environment contributes to most traits has been limited. Even genetic mutations with high penetrance can lead to disparate expressions for each individual. Genetic mutations with narrow expressivity—meaning affected individuals have similar physical manifestations—will still be experienced differently by each individual, thus reducing capacity to make precise predictions from genotypes. Because ‘any risk assessment, and any prediction about sudden, adult-onset symptoms would be extremely speculative’, many believe that using genetic risk factors in employment settings is not scientifically justified.¹³ Further, because tests prove capability by demonstration, they are arguably more reliable—and more fair—than using genetic information: ‘ethical justification of bona fide occupational qualifications seems less problematic with traits (such as eyesight) than as probabilities of phenotypes. . . there are ethical differences between discrimination based on a manifest trait and on a genotype.’¹⁴

Another view is that using genetic information in employment decisions would contribute to fairness if such information provided objective, scientific probabilities of success. In some cases, decisions informed by genetics would not only benefit the employer but could also protect the well-being of the would-be employee; for example, an individual may ‘have genetic-based sensitivities to certain environments.’¹⁵ Although currently prohibited by GINA, genetic information could theoretically be used to inform accommodations for individuals. Perhaps similar to protections required by the Americans with Disabilities Act (ADA),¹⁶ accommodations should be provided as long as they enable the individual to successfully complete required duties without imposing undue burden on the employer.

With additional knowledge about the relationship between genotype and phenotype, it may well become ethically justifiable to use genetic information to select employees in situations that implicate safety of the employee or others or to provide appropriate accommodations. As a hypothesis, if a seizure disorder can be predicted with absolute certainty, a transportation company could ethically deny a driver position to an individual with such a predisposing mutation unless it could be preemp-

12 Mauricio De Castro et al., *Genomic Medicine in the Military*, 1 NPJ GENOMIC MED. 15008 (2016), <http://www.ncbi.nlm.nih.gov/pubmed/29263806>; Gabriel Lázaro-Muñoz & Eric T Juengst, *Challenges for Implementing a PTSD Preventive Genomic Sequencing Program in the U.S. Military*, 47 CASE WEST. RESERVE J. INT. LAW 87–113 (2015), <http://www.ncbi.nlm.nih.gov/pubmed/26401056>.

13 Mark A Rothstein, *Genetic Discrimination in Employment is Indefensible*, 43 HASTINGS CENT. REP. 3–4, 3 (2013), <http://doi.wiley.com/10.1002/hast.219>.

14 Jonathan K Miles, *Genoism by Any Other Name?*, 43 HASTINGS CENT. REP. 4, 4 (2013), <http://doi.wiley.com/10.1002/hast.220>.

15 Mark A Rothstein, *GINA at Ten and the Future of Genetic Nondiscrimination Law*, 48 HASTINGS CENT. REP. 5–7, 6 (2018), <http://doi.wiley.com/10.1002/hast.847>.

16 AMERICANS WITH DISABILITIES ACT, 42 U.S.C. § 12101–12701 (2009).

tively treated or reasonably accommodated. If two candidates for a healthcare clinician position in a location prone to a serious virus are otherwise equally qualified, choosing the one who has genetic resistance to the virus would be in the public health's best interest. As genetic testing becomes more accurate, there may well be situations when the results have relevance for employment decisions.

GINA's prohibition of any classification based on genetic information expresses the current societal consensus that 'basing decisions on even accurate genetic risk is socially unacceptable.'¹⁷ But will societal norms change as knowledge grows? A common fallback is that the science will not justify such discrimination. But it seems incongruous for society to be pouring money into genetic research and testing on the one hand and claiming we will never be able to figure out the genetics of complex traits on the other. Although genetics might—at least for the foreseeable future—be too complex to predict broad and multidimensional characteristics such as intelligence or athleticism, genetic testing of less complex traits such as viral resistance or seizure risk might accurately predict ability to perform a job or be used to help individuals perform a job more safely. In cases like these, there would be some ethical justification for the use of genetic information.

Health Insurance Settings

In contrast to employment settings, the relevance of genetic information in health insurance settings is really not up for debate. Health insurers, particularly those that are for-profit entities, have clear rationale to base eligibility or premiums on genetic information, but whether this is fair is controversial (Table 2). As currently structured, the US health insurance industry has inherent conflicts: the more an individual is genetically (or otherwise) predisposed to disease, the less for-profit insurers desire that individual as a customer. The flip is also true; the more an individual is predisposed to disease, the more they desire comprehensive health insurance—a concept known as adverse selection.¹⁸ Whether you think charging higher premiums on genetic bases is ethical depends in part on your political philosophy; on a communal level, the ethics depends on the society's foundational principles. Libertarians may believe that discrimination based on genetics or health status by for-profit entities is fair, that higher users of healthcare should pay more, and/or that the healthcare insurance industry should function as a free market. If we take risk rating to the extreme, each individual could just pay for the healthcare they use. Another viewpoint is that insurance helps ensure that all individuals have access to basic healthcare, a hallmark of a just society. Similarly, many believe that a just society should ensure that its members have access to education. Pushing the analogy further, some may hold that society should be willing to support sicker individuals who need more healthcare, just as public education mandates more educational supports for those with disabilities. We agree with this view and support strong and broad protections against genetic and health-related discrimination in health insurance settings, especially in the context of increasing capabilities to make

17 Bradley A. Areheart & Jessica L. Roberts, *GINA, Big Data, and the Future of Employee Privacy*, 128 *YALE LAW J.* 544–871, 775 (2019).

18 American Academy of Actuaries, *RISK POOLING: HOW HEALTH INSURANCE IN THE INDIVIDUAL MARKET WORKS* (2017), <https://www.actuary.org/content/risk-pooling-how-health-insurance-individual-market-works-0> (last visited November 19, 2019).

predictions about health using genetic and other sources of information. An individual's access to healthcare should not be penalized for ineluctable genetic risk. Under a public health framework, preserving access to health insurance for individuals with greater genetic risk is consistent with potentially using genetic information to promote safety in employment settings.

Employers as Health Insurers

Complicating matters is the fact that employers play such a big role in providing health insurance in the United States. In 2017, 49 per cent of Americans were covered by employer-based health insurance.¹⁹ Employers that provide health insurance may have interest in genetic information beyond employee efficiency or even the safety of others: they may simply want to reduce healthcare costs for employees and their dependents. Employers can purchase a health plan from a third party insurer or self-insure and cover the healthcare costs of their employees. More employers are turning towards self-insurance to save on healthcare costs, and most Americans with employer-provided insurance are in self-funded plans.²⁰ There are a number of benefits of self-insuring, including exemptions from state insurance regulations²¹ and reduction of healthcare costs, particularly if employees are relatively healthy.²² But employers that self-insure are, for all intents and purposes, health insurers as well. They take on more financial risk for covering unexpected healthcare costs and as such may 'feel the impact of their employees' poor health more acutely.'²³ Healthy employees are also associated with lower replacement, worker compensation, and disability costs.²⁴

Accordingly, just as health insurers are economically incented to insure healthier individuals since they beget lower costs, employers may be economically incented to hire employees who have less risk of developing disease.²⁵ Indeed, a 2005 Wal-Mart Stores, Inc. board memo outlined strategies for recruiting healthier job applicants to cut down on healthcare costs and included a directive that all new jobs should 'include

19 Kaiser Family Foundation, HEALTH INSURANCE COVERAGE OF THE TOTAL POPULATION | THE HENRY J. KAISER FAMILY FOUNDATION KFF; HENRY J KAISER FAMILY FOUNDATION, <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22collid%22:%22Location%22,%22sort%22:%22asc%22%7D> (last visited Aug. 5, 2019).

20 Sara Hansard, MORE SMALLER COMPANIES ARE SELF-INSURING HEALTH BENEFITS | BLOOMBERG LAW BLOOMBERG BNA (2017), <https://info.dgb-online.com/2017/08/09/more-smaller-companies-are-self-insuring-health-benefits/> (last visited Aug. 13, 2019); Bob Herman, *Self-Service Insurance. Insurers Forced to Compete Harder for Self-Insured Customers.*, 45 MOD. HEALTHC. 24–5 (2015), <https://blog.groupresources.com/2017/09/05/more-smaller-companies-are-self-insuring-health-benefits/> (last visited Apr. 26, 2019).

21 National Association of Insurance Commissioners, "White Paper: Stop-Loss Insurance, Self Funding, and the ACA" (2015), https://www.naic.org/documents/SLI_SF.pdf.

22 Hansard, *supra* note 20.

23 Jessica L. Roberts, *Healthism and the Law of Employment Discrimination*, 99 IONA LAW REV. 571–635, 581 (2014).

24 Centers for Disease Control and Prevention (CDC), WORKPLACE HEALTH PROGRAMS CAN IMPACT HEALTH CARE COSTS (2015), <https://www.cdc.gov/workplacehealthpromotion/model/control-costs/index.html> (last visited May 14, 2019).

25 Jessica L. Roberts, *GINA's Limits or Something More? The Need for Greater Protection of Employee Health-Related Information*, 14 AM. J. BIOETH. 45–48 (2014), <http://www.ncbi.nlm.nih.gov/pubmed/25325811> (last visited Apr. 26, 2019); Roberts, *supra* note 23; Ron Z. Goetzel et al., *Ten Modifiable Health Risk Factors Are Linked To More Than One-Fifth Of Employer-Employee Health Care Spending*, 31 HEALTH AFF. 2474–2484 (2012), <http://www.ncbi.nlm.nih.gov/pubmed/23129678> (last visited Apr. 26, 2019).

some physical activity (e.g., all cashiers do some cart-gathering).²⁶ Why? 1.3 per cent of those covered by employer-based insurance account for almost 20 per cent of healthcare spending; often these individuals have serious conditions like HIV, MS, rheumatoid arthritis, cancer, and diabetes.²⁷ To reduce healthcare costs and keep employees healthy, many large employers will turn their attention to high cost claimants.²⁸ Although the science is not there yet, genetic information may soon allow identification of employees at high risk for many health problems.²⁹ As the value of genetic information grows and as expensive and personalized therapies become a reality, the rationale and incentives for health insurers and employers to discriminate using genetic information will increase. However, as stated above, we believe that protections against genetic discrimination should remain broad and strong in health insurance settings. Further, ethical concerns arise when employers are interested in employees' (and their dependent's) health, for reasons that have nothing to do with their ability to perform the job well or safely.

PART II. CURRENT LAWS

In Part II, we analyze the strengths and weaknesses of US laws that collectively provide protections against genetic discrimination in employment and health insurance settings. We first analyze GINA but also briefly review laws that prohibit employment and health insurance discrimination based on health status, including the ADA, the Health Insurance Portability and Accountability Act of 1996 (HIPAA),³⁰ and the ACA. These are important in the context of genetic conditions that have become 'manifest' or symptomatic. We also discuss the importance and limits of privacy protections.

Genetic Information Nondiscrimination Act

GINA, a hybrid privacy and anti-discrimination federal law intended to 'prohibit discrimination on the basis of genetic information with respect to health insurance and employment', was enacted in 2008.³¹ Before that, a patchwork of state laws existed providing some protections against genetic discrimination, but their scope and applicability varied significantly.³² GINA aimed to allay the public's concerns about genetic discrimination so that people could avail themselves of genetic testing in research or

26 Steven Greenhouse & Michael Barbaro, *Wal-Mart Memo Suggests Ways to Cut Employee Benefit Costs*, THE NEW YORK TIMES, October 26, 2005.

27 Drew Altman, *A Small Group of Patients Account for a Whole Lot of Spending*, AXIOS, July 29, 2019, <https://www.axios.com/drug-prices-health-care-costs-spending-employers-63a65abc-0148-4f98-bd39-b30e4d3c9caf.html>.

28 Stephen Miller, *MANAGING HIGH-COST CLAIMANTS IS EMPLOYERS' TOP HEALTH SAVINGS STRATEGY* SOCIETY FOR HUMAN RESOURCE MANAGEMENT (SHRM) July 26, 2018, <https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/managing-high-cost-claimants.aspx> (last visited May 14, 2019).

29 Khera et al., *supra* note 2; Inouye et al., *supra* note 2.

30 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT, (1996).

31 GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008, Preamble (2008).

32 Amanda Brower & Katherine T Adams, *What GINA Wants, Will GINA Get?*, 6 BIOTECHNOL. HEALTHC. 30-2 (2009), <http://www.ncbi.nlm.nih.gov/pubmed/22478763>; National Human Genome Research Institute, *GENETIC DISCRIMINATION* (2017), available at <https://www.genome.gov/about-genomics/policy-issues/Genetic-Discrimination> (updated September 24, 2019).

clinical settings. It was a preemptive law, addressing the potential for genetic discrimination before it was a widespread problem.³³ Now over a decade old, it is worth examining protections against genetic discrimination in the United States, in the emerging context in which the accuracy and predictive power of genetic testing is increasing.

GINA has a relatively broad definition of ‘genetic information’ which includes not only an individual’s genetic tests but also family history of disease and/or genetic tests.³⁴ GINA protects individuals from discrimination on the basis of genetic predispositions but also regulates the privacy of genetic information in order to prevent its misuse.³⁵ GINA prohibits health insurance issuers from using genetic information for underwriting purposes, including for the determination of eligibility or the computation of premiums and from requesting or acquiring genetic information for such purposes. Medical underwriting, as one scholar has astutely noted, could ‘more accurately be called *medical underinsuring*’.³⁶ Likewise, GINA bars employers from basing employment decisions on genetic information or from requesting, requiring, or purchasing it.

Although its protections are broad, GINA does not prohibit all forms of genetic discrimination.³⁷ As employers with fewer than 15 employees are not subject to GINA regulations,³⁸ at least 10 per cent of the private sector employed population is not even covered by GINA’s protections against employment discrimination,³⁹ but some states do extend genetic discrimination protections to smaller employers. Although US military service members and federal employees are not protected by GINA, an executive order protects federal employees from genetic discrimination, and the Department of Defense has its own genetic discrimination policies that may provide protection as well.⁴⁰

On the insurance side, GINA does not prohibit life insurance companies, disability insurance companies, or long-term care insurers from using genetic information to deny coverage or raise premiums. The health insurance protections

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- 33 Jennifer S Bard, *When Public Health and Genetic Privacy Collide: Positive and Normative Theories Explaining How ACA’s Expansion of Corporate Wellness Programs Conflicts with GINA’s Privacy Rules*, 39 J. LAW. MED. ETHICS 469–87 (2011), <http://journals.sagepub.com/doi/10.1111/j.1748-720X.2011.00615.x>; Jessica L. Roberts, WILL THE RECENT WORKPLACE WELLNESS BILL REALLY UNDERMINE EMPLOYEE HEALTH PRIVACY? PETRIE FLOM CENTER BILL OF HEALTH BLOG (March 15, 2017), <https://blog.petrieflom.law.harvard.edu/2017/03/15/will-the-recent-workplace-wellness-bill-really-undermine-employee-health-privacy/>; Rothstein, *supra* note 15.
- 34 GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008, *supra* note 31 at Section 201.
- 35 Laura DeFrancesco, *To Share is Human*, 33 NAT. BIOTECHNOL. 796–800 (2015); Jessica L. Roberts, *Protecting Privacy to Prevent Discrimination*, 56 WILLIAM MARY LAW REV. 2097–2174 (2015).
- 36 Donald W. Light, *The Practice and Ethics of Risk-Rated Health Insurance*, 267 JAMA 2503–2508, 2503 (1992), <https://www.ncbi.nlm.nih.gov/pubmed/1573728>.
- 37 DeFrancesco, *supra* note 35; Robert C. Green, Denise Lautenbach & Amy L. McGuire, *GINA, Genetic Discrimination, and Genomic Medicine*, 372 N. ENGL. J. MED. 397–399 (2015), <http://www.ncbi.nlm.nih.gov/pubmed/25629736>.
- 38 Green, Lautenbach, and McGuire, *supra* note 37.
- 39 U.S. Bureau of Labor Statistics, BUSINESS EMPLOYMENT DYNAMICS 2018. TABLE F. DISTRIBUTION OF PRIVATE SECTOR EMPLOYMENT BY FIRM SIZE CLASS: 1993/Q1 THROUGH 2018/Q1, NOT SEASONALLY ADJUSTED (2018), www.bls.gov/bdm/bdmfirmsize.htm (last visited Apr. 26, 2019).
- 40 De Castro et al., *supra* note 12; Genetic Alliance, the Genetics and Public Policy Center at Johns Hopkins University and the National Coalition for Health Professional Education in Genetics, *GINA & You* (2010), http://www.ginahelp.org/GINA_you.pdf.

also do not apply to the Tricare military health system, the Indian Health Service, the Veterans Health Administration, or the Federal Employees Health Benefits Program, but these organizations have their own genetic discrimination policies.⁴¹ There are publicized reports of genetic discrimination in life insurance settings.⁴² Some states provide more protections: 17 states have laws that provide protections against discrimination in life insurance settings, 17 states have additional protections in disability settings, and eight states restrict the use of genetic information for long-term care insurance.⁴³ California also has a law which prohibits genetic discrimination in emergency medical services, housing, mortgage lending, and education contexts.⁴⁴

Although GINA prohibits discrimination based on genetic predisposition to disease, Section 210 of the law expressly states that employers who use medical information ‘about a manifested disease, disorder, or pathological condition’ shall not be considered in violation of the law, even if the condition has a genetic basis.⁴⁵ Therefore, from a practical standpoint, particularly in an era in which traditional clinical tests, biomarkers, and imaging are often used in conjunction with genetic testing to forecast disease, GINA is limited in scope. Even defining when a genetic predisposition has become manifest can be challenging.⁴⁶ A middle-aged man who tests positive for an early-onset familial Alzheimer’s disease gene would likely not be covered by GINA if imaging also showed the accumulation of amyloid plaques, nor would a woman diagnosed with breast cancer, even if it has a genetic basis.

To summarize, although GINA provides protections against discrimination based on genetic information in health insurance and employment settings, the law has significant limitations. Most notably, the law provides no protections against genetic discrimination for life insurance, disability insurance, or long-term care insurance. Small employers (with under 15 employees) do not need to comply with GINA. Further, GINA’s protections only apply to individuals who have a genetic result or positive test that exists in the absence of any overt symptoms of the disease or condition. If a positive genetic test precipitates further testing that reveals previously unnoticed clinical manifestations of disease (even at its earliest stages), GINA would not apply.

Complementary Protections: ADA, HIPAA, and ACA

Since GINA does not protect individuals that have manifestations of genetic disease, to fully assess protections from genetic discrimination in the United States, it is necessary to examine other federal laws which provide complementary protections to GINA

41 Genetic Alliance, the Genetics and Public Policy Center at Johns Hopkins University and the National Coalition for Health Professional Education in Genetics, *supra* note 40.

42 Christina Farr, *If You Want Life Insurance, Think Twice before Getting a Genetic Test*, FAST COMPANY, 2016; Saira Mohammed et al., *Genetic Insurance Discrimination in Sudden Arrhythmia Death Syndromes: Empirical Evidence From a Cross-Sectional Survey in North America*, 10 CIRC. CARDIOVASC. GENET. (2017), <https://www.ahajournals.org/doi/10.1161/CIRCGENETICS.116.001442>.

43 National Human Genome Research Institute, *supra* note 32.

44 *Id.*

45 GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008, *supra* note 31 at Section 210.

46 Anya E. R. Prince & Benjamin E. Berkman, *When Does an Illness Begin: Genetic Discrimination and Disease Manifestation*, 40 J. LAW, MED. ETHICS 655–664 (2012), <http://www.ncbi.nlm.nih.gov/pubmed/23061591>.

against employment and insurance discrimination in the more general context of health status. These include the ADA in employment settings and HIPAA and the ACA in the context of health insurance.

The ADA prohibits discrimination based on disability status, defining disability as a physical or mental impairment that substantially limits one or more major life activities, a person who has a history of such an impairment, or a person who is regarded as having such an impairment. Depending on the specific details inherent to any particular case, a positive genetic test and/or asymptomatic disease could arguably fall under the law's purview in the 'regarded as' category.⁴⁷ In *Bragdon v. Abbott*, the Supreme Court ruled that an asymptomatic individual with HIV met the ADA's definition of having a disability.⁴⁸ However, to strengthen the law's protections, one scholar has proposed that the ADA should be amended to prohibit discrimination against those who do not have current disabilities but who are perceived to be at risk for developing impairments in the future.⁴⁹ The ADA prohibits private employers with over 15 employees, state and local governments, employment agencies, and labor unions from discriminating against qualified individuals with disabilities.⁵⁰ Like GINA, the ADA includes both privacy and anti-discrimination components.⁵¹

The ADA is based on the justifiable premise that an individual's disability should not be used as a basis for discrimination if the person is able to perform the job in question. However, the ADA does not prevent employers from discriminating against individuals whose disabilities prevent them from performing the essential functions of a job with or without reasonable accommodation, as these individuals would not meet the definition of 'qualified individuals'. Employers are required to make accommodations unless they impose an undue hardship.⁵² The ADA also allows employers to impose a qualification standard that individuals not pose a 'direct threat', defined as 'a significant risk to the health or safety of others that cannot be eliminated by reasonable accommodation.'⁵³ A direct threat defense also applies if the employee's own health or safety would be jeopardized.⁵⁴

In health insurance settings, legal protections against discrimination based on pre-existing conditions, often referred to as pre-existing condition protections, vary

47 Eugenia Liu, *Bragdon v. Abbott: Extending the Americans with Disabilities Act to Asymptomatic Individuals*, 3 J. HEALTH CARE LAW POLICY 382-408 (2000), <https://www.ncbi.nlm.nih.gov/pubmed/15015486>.

48 *Bragdon v. Abbott*, 524 U.S. 624 (1998).

49 Sharona Hoffman, *Big Data and the Americans with Disabilities Act* 68 Hastings Law J. 777-794 (2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2841431.

50 AMERICANS WITH DISABILITIES ACT, *supra* note 16 at Section 12111.

51 U.S. Equal Employment Opportunity Commission, QUESTIONS AND ANSWERS: ENFORCEMENT GUIDANCE ON DISABILITY-RELATED INQUIRIES AND MEDICAL EXAMINATIONS OF EMPLOYEES UNDER THE AMERICANS WITH DISABILITIES ACT (2019), <https://www.eeoc.gov/policy/docs/qanda-inquiries.html> (last visited May 14, 2019).

52 AMERICANS WITH DISABILITIES ACT, *supra* note 16 at Section 12111 (101).

53 *Id.* at Section 12111 (101).

54 Mark Barnes, Kimberlee A Cleaveland & Patrik S Florencio, *Chevron v Echazabal: Public Health Issues Raised by the "Threat-to-Self" Defense to Adverse Employment Actions*, 93 AM. J. PUBLIC HEALTH 536-40 (2003), <http://www.ncbi.nlm.nih.gov/pubmed/12660192>.

depending on the type of health insurance.⁵⁵ Medicare and Medicaid do not deny eligibility or charge higher premiums for people with pre-existing conditions.⁵⁶ Prior to passage of the ACA, individuals covered by employer-based insurance were protected by provisions in HIPAA.⁵⁷ Title I of HIPAA prohibits denial of eligibility or benefits based on health factors, which include health status, medical condition, claims experience, and genetic information. HIPAA does not allow pre-existing exclusions based on genetic information in the absence of a diagnosis.

HIPAA's protections have limits. Although HIPAA prohibits individual premiums from being based on health factors, insurers can charge higher rates for group plans based on collective health status.⁵⁸ With some qualifications, HIPAA allows time-limited exclusions (12 or 18 months for late enrollees) relating to a pre-existing physical or mental condition for which advice, diagnosis, care, or treatment was sought or received within the 6-month period ending on the enrollment date. HIPAA's discrimination protections apply within a group of 'similarly situated' individuals, but not across different groups.⁵⁹ Although HIPAA provided many protections, it did not limit what insurers could charge individuals who left the group market; these policies often became unattainable because of their expense.⁶⁰ Private for-profit companies who offered insurance policies through the pre-ACA individual market might exclude coverage for pre-existing conditions, cap coverage, charge higher prices for coverage, or even deny coverage.⁶¹

Since 2014, the ACA has prohibited health insurance companies from denying coverage or basing premiums on a pre-existing condition. Prior to the ACA's enactment, health plans in the individual market 'used individual medical underwriting to assess an applicant's health status and charged premiums to reflect an individual's underlying risk.'⁶² The ACA's mandate for insurers to cover pre-existing conditions is made possible by other provisions in the law, including those that encourage enrollment. By imposing a financial penalty on individuals without health insurance (which has since been repealed) and expanding Medicaid eligibility and creating incentives for business to provide health benefits, the ACA increased the number of insured Americans.⁶³ Prior to the law's passage, individuals from middle-class families with health insurance who got sick complained of skyrocketing premiums and the cancellation of their insurance.⁶⁴ Forty-one states allowed exclusion periods for pre-existing conditions ranging from 6 to 36 months, in which insurers were not required to pay for care related to the

55 Julie Rovner, *FACT CHECK: Who's Right About Protections For Pre-Existing Conditions?*, KAISER HEALTH NEWS (KHN), 2018, <https://khn.org/news/fact-check-whos-right-on-protections-for-preexisting-conditions-its-complicated/>.

56 *Id.*

57 *Id.*

58 U.S. Department of Labor; Employee Benefits Security Administration, *FAQS ON HIPAA PORTABILITY AND NONDISCRIMINATION REQUIREMENTS FOR WORKERS*, <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/hipaa-consumer.pdf> (last visited May 14, 2019).

59 *Id.*

60 Rovner, *supra* note 55.

61 Areheart and Roberts, *supra* note 17; Light, *supra* note 36.

62 American Academy of Actuaries, *supra* note 18.

63 Robert Pear & David M. Herszenhorn, *Obama hails vote on health care as answering "the call of history,"* THE NEW YORK TIMES, March 21, 2010.

64 *Id.*

condition; nine states and D.C. allowed insurers to impose permanent exclusions.⁶⁵ Since the passage of the ACA, personal bankruptcy filings have decreased from 1.5 million annually in 2010 to about 770,000 in 2016.⁶⁶ The pre-existing protections of the ACA are so strong that some have rendered GINA's health insurance protections irrelevant.⁶⁷

Importance and Limits of Privacy Protections

A recent review of all published and unpublished federal court decisions involving GINA claims from 2009 to 2018 concluded that although there have been a number of cases involving claims of genetic discrimination, there have been no successful claims filed for discrimination based on genetic test results.⁶⁸ Our own research indicates that the vast majority of GINA cases that are prosecuted by the EEOC in employment settings are alleged violations of the privacy clauses. Many include illegal requests for information about family history of disease. These analyses suggest that genetic discrimination is still not a pervasive problem at this time. However, genetic testing has only recently experienced rapid growth in availability and spending; the clinical sequencing market has a 28 per cent compound annual growth rate and expected to reach \$7.7 billion by 2020.⁶⁹ Perhaps the law just has not yet been fully put to the test. But analysis of the cases also reveals GINA's power in safeguarding genetic privacy for employees.⁷⁰ Employers cannot use genetic information to discriminate if they do not have access to such information.

The 2015 'Devious Defecator' case, *Lowe V. Atlas Logistics Group Retail Servs.*, demonstrates GINA's privacy protections.⁷¹ Atlas asked two employees to provide cheek swabs for DNA testing after feces was found on the company's warehouse floor; the men felt that Atlas had violated GINA by requesting their DNA, even though they were not a match, and filed suit.⁷² Atlas claimed it did not break the law because genetic information, as defined by GINA, only refers to information relating to an individual's propensity for disease. The court rejected Atlas' interpretation and declared its actions a violation of employee privacy. The employees' attorney told jurors that in awarding damages, they had to send a clear message to employers across the country: 'That requesting DNA causes harm. That it caused harm here. And that they have to pay for harm.'⁷³ The jury awarded the employees with \$2.25 million dollars in compensatory and punitive damages.⁷⁴

65 Sandy Ahn, HOW ACCESSIBLE AND AFFORDABLE WERE INDIVIDUAL MARKET HEALTH PLANS BEFORE THE AFFORDABLE CARE ACT? DEPENDS WHERE YOU LIVED (2017), <https://www.issueab.org/resource/how-accessible-and-affordable-were-individual-market-health-plans-before-the-affordable-care-act-depends-where-you-lived.html>.

66 Allen St. John, *How Obamacare Helped Slash Personal Bankruptcy by 50%*, MONEY, May 4, 2017, <http://money.com/money/4765443/obamacare-bankruptcy-decline/>.

67 Areheart and Roberts, *supra* note 17 at 747.

68 *Id.* at 714.

69 Kathryn A. Phillips et al., *Genetic Test Availability And Spending: Where Are We Now? Where Are We Going?*, 37 HEALTH AFF. 710–716, 714 (2018), <http://www.ncbi.nlm.nih.gov/pubmed/29733704>.

70 Areheart and Roberts, *supra* note 17.

71 *Lowe v. Atlas Logistics Group Retail Services*, 102 F.Supp.3d 1360 (2015).

72 Gina Kolata, "Devious Defecator" Case Tests Genetics Law, THE NEW YORK TIMES, May 29, 2015.

73 Nina Farahany, *Jurors award \$2.25 m in "devious defecator" case*, THE WASHINGTON POST, June 23, 2015.

74 *Id.*

Yet there are exceptions to GINA's privacy clauses, which may enable the opportunity for discrimination. Employers can legally request genetic information from employees in certain situations, such as to assure work conditions, which may expose employees to toxins, do not cause genomic damage or as part of quality control measures in forensic laboratories that deal with human samples. Employer-based wellness programs are also allowed to request genetic and other (non-job related) health information from employees, but the employee must provide voluntary, prior written authorization, and any individually identifiable genetic information must not be disclosed back to the employer.

While there are many federal and state protections surrounding privacy and confidentiality of health information, there are gaps in protection. HIPAA provides broad protections relating to the privacy of health information, but the HIPAA Privacy and Security rules only apply to covered entities, which include healthcare providers, health plans, and healthcare clearinghouses, and the business associates of covered entities.⁷⁵ Some entities that collect private health information are not subject to HIPAA, including direct to consumer genetic testing companies and health apps, leaving a potentially significant gap in protection.⁷⁶

Self-disclosure may also be considered a gap in protection: as genetic testing becomes less expensive, the possibility that employees will share genetic information becomes greater. GINA may even give people a false sense of security, as discrimination can be hard to prove. Although privacy of genetic and health information is a critically important means of preventing discrimination, complete privacy may not even be a realistic expectation in an era of big data and genetic reidentification capabilities. Thus, some feel that 'education and legislation aimed less at protecting privacy and more at preventing discrimination will be key'.⁷⁷

PART III. RECOMMENDATIONS

In this section, we consider current and future challenges to the legal framework that prohibits genetic discrimination in employment and health insurance settings and, based on our ethical analysis, make recommendations for responding to these challenges. First, we acknowledge that as the accuracy and predictive power of genetic testing increases, uses of genetic information by employers may be ethically justified in specific circumstances, and additional exceptions to GINA may eventually be warranted. However, any modifications to current laws could only be ethically made after a deliberative and inclusive legislative process, since individuals in the United States currently consent to genetic testing with the assurance that genetic discrimination in employment settings is prohibited by federal law. In the context of health insurance, including employer-based health insurance, we stress the prioritization and safeguard-

75 U.S. Department of Health and Human Services, SUMMARY OF THE HIPAA PRIVACY RULE (2013), <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html> (last visited May 1, 2019); U.S. Department of Health and Human Services, SUMMARY OF THE HIPAA SECURITY RULE (2013), <https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html> (last visited May 1, 2019).

76 Rachele M Hendricks-Sturup, Anya E R Prince & Christine Y Lu, *Direct-to-Consumer Genetic Testing and Potential Loopholes in Protecting Consumer Privacy and Nondiscrimination*, JAMA (2019), <http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2019.3384>.

77 Eric E Schadt, *The changing privacy landscape in the era of big data*, 8 MOL. SYST. BIOL. 1–3, 2 (2012), <http://msb.embopress.org/cgi/doi/10.1038/msb.2012.47>.

ing of strict protections against discrimination based not only on genetic information but on health status more broadly. Under a public health framework, limited uses of accurate genetic information to improve health and safety in employment settings reconcile with preventing the use of genetic information for insurance discrimination purposes. We also assert that privacy protections for genetic information must be preserved, as they are extremely important, particularly in employment settings. These recommendations have implications for the current US policy debate on healthcare.

Carefully consider future exceptions to GINA in employment settings

The ADA and GINA embody our society's aspirational ideal that genetic information and health/disability status should not be used against employees or job applicants unless it affects their ability to do the job. The EEOC maintains that genetic discrimination in employment settings is illegal because 'genetic information is not relevant to an individual's current ability to work'⁷⁸ and that '[t]he prohibition on the use of genetic information in employment decision-making is absolute, since the possibility that someone may develop a disease or disorder in the future has nothing to do with his or her current ability to perform a job.'⁷⁹ The EEOC has considered adding an exception to allow employers to request genetic information as part of employment screening in some circumstances but did not find evidence of the need for such an exception.⁸⁰

Notwithstanding the limited and specific exceptions in which employers can currently legally request and/or use genetic information including an allowance to acquire employee genetic information to monitor biological effects of toxic substances in the workplace,⁸¹ GINA generally precludes the use of genetic information for any purpose. This includes positive or negative discrimination (whether for benefit of employee or others or for accommodation purposes). Thus, GINA can be viewed as an anticlassification law, but not an antisubordination law. The anticlassification principle forbids classifying people on the basis of specified categories, but the antisubordination principle 'allows classification. . . to the extent [it] is intended to challenge group subordination.'⁸² In contrast, the ADA specifies not only that employers must not discriminate against those with disabilities but that they must accommodate them unless such accommodation imposes undue hardship. In the future, we may understand that individuals with certain genotypes would perform better with certain accommodations; the ethical analysis would be dependent on the details of such a case, but requesting and/or using genetic information to inform accommodation may indeed be justified in specific circumstances.

78 U.S. Equal Employment Opportunity Commission, GENETIC INFORMATION DISCRIMINATION, <https://www.eeoc.gov/laws/types/genetic.cfm> (last visited Apr. 26, 2019).

79 U.S. Equal Employment Opportunity Commission, BACKGROUND INFORMATION FOR EEOC FINAL RULE ON TITLE II OF THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008, <https://www.eeoc.gov/laws/regulations/gina-background.cfm> (last visited Apr. 26, 2019) "Background information."

80 Melanie Trotman, *New Battles in the Workplace—Genetic Tests Create Pitfalls for Employers*, THE WALL STREET JOURNAL, Eastern edition, B1 July 23, 2013.

81 GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008, *supra* note 31 at Section 202 (b) (5).

82 Bradley A. Areheart, *The Anticlassification Turn in Employment Discrimination Law*, 63 ALA. LAW REV. 955–1006, 955 (2012), <https://ssrn.com/abstract=1887772>.

Another difference between the ADA and GINA is that if an individual poses a risk to others in the workplace (or themselves), the ADA permits a 'direct threat' defense. In the future, scientific evidence may suggest that an individual's genotype would cause the person to be a direct threat to themselves or others if they assume certain duties. Although the details of and evidence relating to any specific case would be critical for rigorous ethical analysis, if the risk could not be mitigated by reasonable accommodation, the use of genetic information in specific circumstances related to 'direct threat' situations would be justifiable. Others concur that adding a direct threat defense provision to GINA is appropriate.⁸³ In the future, GINA may be appropriately modified to add a 'direct threat' defense provision to account for those specific cases. With advances in knowledge and technology, we believe that specific exceptions for allowable uses of genetic information in employment settings may indeed become ethical and justifiable if they are proved relevant. However, we must acknowledge that consumers, patients, and research participants have consented to genetic testing under the assurance that genetic discrimination is forbidden in employment settings. Any future allowances of genetic discrimination in employment settings should only be granted through a deliberative legislative process and ought to focus on identifying accommodations and support rather than being used to deny opportunity. Perhaps one of the biggest ethical issues— independent of the increasing accuracy or relevance of genetic information due to technology advances—is that the United States has to live up to the contractual expectations that it has established with the enactment of GINA.

Preserve Strict Prohibitions on Genetic Discrimination in Health Insurance Settings

On the other hand, we believe that genetic discrimination should never be allowed in health insurance settings. Providing citizens with access to healthcare should be a priority of a just society. Passage of GINA indicates broad, bipartisan support that genetic status should not be used to discriminate in health insurance settings. Given the ethical imperative to ensure that individuals are not barred from healthcare based on genetic or other health status, this has important implications for current discussions on regulation of health insurance in the United States and on weighing the advantages and disadvantages of the country's current reliance on for-profit insurers (including employers). Within the confines of the law, these entities will act in ways that enable them to increase revenues and reduce costs.

The desire for employment opportunities to be based only on ability to perform the job may become compromised by the US dependence on employer-provided health insurance. A national or state-based universal access health insurance system might afford citizens better protection against genetic and health discrimination by health insurers and employers. A system that is so dependent on for-profit insurers will never escape the inherent tension that individuals who are either predisposed to disease themselves or who have dependents at high risk will be less desirable insureds—or insured employees. This consideration may become more important over time as the predictive power of genetic information increases. If individuals are to benefit from our

83 Jessica L Roberts et al., *Evaluating NFL Player Health and Performance: Legal and Ethical Issues*, 165 UNIV. PA. LAW REV. 227–314, 311–312 (2017), <https://papers.ssrn.com/abstract=2905718>.

society's significant investment in genetic research, we must ensure that everyone can access the 'precision medicine' that is promised.

Prioritize and Safeguard Pre-existing Condition Protections

As described above, traditional health insurers are currently constrained by the ACA's pre-existing condition protections, which prevent them from charging higher premiums based on health status.⁸⁴ Because GINA only prevents discrimination based on genetic information, but not manifest disease, the ACA's pre-existing protections are extremely important to individuals who have a condition that is already symptomatic. They are also important to healthy people who are considering genetic testing: 'without strong insurance protections for pre-existing conditions, [healthy] people will have to weigh the benefits of early tests against the risk that they'll be priced out of the normal health insurance market.'⁸⁵ Although pre-existing condition protections in health insurance settings are the most popular aspect of the ACA⁸⁶ and they currently remain in place, recent executive, legislative, and judicial actions demonstrate that these provisions cannot be taken for granted.

Although ultimately unsuccessful in attempts to completely repeal the ACA, the 2017 Republican Congress was able to legislatively abolish the ACA's individual tax penalty for going without health insurance. The mandate and its associated penalty were intended to incent more people to purchase health insurance so that insurers could leverage larger risk pools to keep premiums down.⁸⁷ Without the penalty, healthier, younger individuals may forego health insurance or opt for short-term plans, which are exempt from some of the ACA requirements including pre-existing condition protections.⁸⁸ In light of the repeal of the tax penalty associated with the individual mandate, 20 Republican state attorneys general and governors filed suit in February 2018 joining *Texas v. United States of America* and challenging the constitutionality of the ACA.⁸⁹ Going against long-standing traditions, Attorney General Jeff Sessions announced in 2018 that the US Justice Department would not defend the constitutionality of certain provisions of the ACA, namely, those that guarantee issuance of coverage, referring to the essential health benefits, and the prohibition of discriminatory rates, otherwise

84 Tami Luhby, *Will Obamacare Survive the Tax Bill?*, CNNMONEY, 2017, <https://money.cnn.com/2017/12/15/news/economy/obamacare-individual-mandate-tax/index.html>.

85 Michael White, *The Future of Medicine Depends on Protections for Pre-Existing Conditions*, PACIFIC STANDARD, 2017, <https://psmag.com/social-justice/the-future-of-medicine-depends-on-protections-for-pre-existing-conditions>.

86 Kaiser Family Foundation, MOST AMERICANS—ACROSS PARTIES—SAY 2018 CANDIDATES' POSITION ON PRE-EXISTING CONDITION PROTECTIONS WILL MATTER TO THEIR VOTE; DO NOT WANT SUPREME COURT TO OVERTURN THESE ACA PROTECTIONS (2018), <https://www.kff.org/health-reform/press-release/poll-july-2018-changes-to-affordable-care-act-health-care-in-midterms-and-the-supreme-court/>.

87 Luhby, *supra* note 84; Julie Rovner & Julie Appleby, *Administration Challenges ACA's Preexisting Protections in Court*, THE WASHINGTON POST, June 8, 2018.

88 Tami Luhby, *People with Pre-Existing Conditions Could Face Tough Times Ahead*, CNNMONEY, 2018, <https://money.cnn.com/2018/03/01/news/economy/pre-existing-conditions-trump/index.html>; Robert Pear, *Trump's Short-Term Health Insurance Policies Quickly Run Into Headwinds*, THE NEW YORK TIMES, August 6, 2018; Karen Pollitz et al., *UNDERSTANDING SHORT-TERM LIMITED DURATION HEALTH INSURANCE* (2018), <https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/>.

89 Rovner and Appleby, *supra* note 87; Katie Keith, *Texas v. United States Oral Arguments in July*, HEALTH AFFAIRS BLOG, 2019, <https://www.healthaffairs.org/doi/10.1377/hblog20190412.997469/full/>.

known as pre-existing condition protections. In December 2018, a judge sided with the plaintiffs and invalidated the ACA, without an injunction: the law stands while it makes its way through the courts.⁹⁰ Some feel that the ACA, and its pre-existing condition protections, will ultimately be upheld as constitutional,⁹¹ but others warn against complacency.⁹² Recent developments lend support to the latter position.⁹³ In a March 2019 letter to the Fifth Circuit Court of Appeals, the Justice Department indicated its support for the district court's judgment to invalidate the ACA.

Perhaps evidencing the popularity of the pre-existing condition protections, a group of Republican senators introduced a bill, S. 3388, in August 2018 called 'Ensuring Coverage for Patients with Pre-existing Conditions Act'. The proposed law would amend HIPAA to include clauses that would prevent group health plans or insurers of group or individual health insurance from denying coverage based on health status, genetic information, medical condition (including physical or mental illness), or medical history. The bill also includes pricing limits and anti-discrimination rules for wellness programs. Although this sounds reassuring, there is a huge loophole in that the bill does not require insurers to cover the treatment of the pre-existing condition.⁹⁴ More than 25 patient and consumer groups issued a statement expressing concern that the Senate bill would not sufficiently protect patients with pre-existing conditions.⁹⁵ Other bills, such as S.1125, the Protect Act, and H.R. 692, the Pre-existing Conditions Protection Act of 2019, have also been introduced, but patient groups remain concerned that the policies outlined in these bills fall far short of the comprehensive protections and coverage expansion included in current law.⁹⁶ In fact, many different proposals from the current Republican majority to replace the ACA would weaken pre-existing protections.⁹⁷ In contrast, patient groups expressed support for the Democrats' bill, 'Protecting Pre-Existing Conditions and Making Health Care More Affordable Act of 2019' (H.R.1884), which was referred to committees in March

90 Lawrence O. Gostin, *Texas v. United States: The Affordable Care Act Is Constitutional and Will Remain So*, 321 JAMA 332–333 (2019), <http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2018.21584>.

91 *Id.*

92 Tara Law, *A Judge Ruled Obamacare is Unconstitutional, Here's How It Could Impact Your Health Insurance*, Time.com, 2018, <http://time.com/5482004/affordable-care-act-court-ruling/>.

93 Abby Goodnough, *Appeals Court Seems Skeptical About Constitutionality of Obamacare Mandate*, THE NEW YORK TIMES, July 9, 2019, <https://www.nytimes.com/2019/07/09/health/obamacare-appeals-court.html>.

94 Michael Hiltzik, *The GOP Claims Its Proposal Would Protect People with Preexisting Conditions. That's a lie*, THE LOS ANGELES TIMES, August 28, 2018; Julie Rovner, *What a ruling in Texas v. United States could mean for health care*, NPR.org, 2018, <https://www.npr.org/2018/09/05/644973437/what-a-ruling-in-texas-v-united-states-could-mean-for-health-care>.

95 American Lung Association, *SENATE HEALTH CARE BILL WOULD NOT SUFFICIENTLY PROTECT PATIENTS WITH PRE-EXISTING CONDITIONS* (2018), <https://www.lung.org/about-us/media/press-releases/senate-health-care-bill-would.html> (last visited May 14, 2019).

96 American Heart Association and other patient advocacy groups, *LETTER TO THE HONORABLE FRANK PALLONE AND THE HONORABLE GREG WALDEN, CHAIRMAN AND RANKING MEMBER, HOUSE ENERGY & COMMERCE COMMITTEE* (2019), <https://www.marchofdimers.org/materials/05-08-19GenericRe-IntroLetterBurrtoCoalition.pdf> (last visited Aug. 7, 2019).

97 Jon Greenberg, *Republican Pre-Existing Protections Leave Some Vulnerable*, POLITIFACT 2019, <https://www.politifact.com/truth-o-meter/statements/2019/apr/01/mick-mulvaney/republican-pre-existing-protections-leave-some-vul/>.

2019.⁹⁸ Although it remains to be seen how healthcare reform in the United States will evolve, if the ACA is abandoned and pre-existing condition protections are diminished, protections from genetic discrimination in insurance settings would also decrease, as GINA does not apply once symptoms appear. The US Congress will likely wait until after the 2020 elections to turn its attention back to healthcare reform. Debate on different options should address how each potential plan addresses the potential for health discrimination by health insurers.

Uphold Privacy Protections in Employment Settings

Evidencing the fact that US employers are financially and otherwise incented to keep employees healthy, they have increasingly adopted workplace wellness programs to improve employee health, reduce healthcare costs, and increase employee productivity.⁹⁹ Touted as beneficial to both employers and employees, these programs have been encouraged by provisions in the ACA, which allow employers to make 30 or 50 per cent of an employee's premiums contingent on achieving health objectives or tobacco cessation, respectively.¹⁰⁰ Although their efficacy is debated,¹⁰¹ wellness programs have been especially popular with self-funded employers.¹⁰² Some advise that employer-based wellness programs would be smart to 'focus on those individuals with elevated risks for or already having poor health status or health behaviors'.¹⁰³ Certain companies are providing genetic testing through wellness programs as a benefit to their employees and as a way to reduce healthcare costs,¹⁰⁴ although some programs have encountered employee resistance amidst privacy concerns.¹⁰⁵

Employer-based wellness programs are pertinent to a discussion about genetic and health-related discrimination because they are a legal carveout in which employers can request genetic and other health information from employees, although as noted above, the programs must be run by third parties, and no individually identifiable information

98 American Heart Association, 26 PATIENT GROUPS SUPPORT BILL TO STABILIZE AND STRENGTHEN THE AFFORDABLE CARE ACT PROTECTING PRE-EXISTING CONDITIONS AND MAKING HEALTH CARE MORE AFFORDABLE ACT OF 2019 INTRODUCED IN HOUSE OF REPRESENTATIVES (2019), <http://newsroom.heart.org/news/26-patient-groups-support-bill-to-stabilize-and-strengthen-the-affordable-care-act> (last visited May 14, 2019).

99 Katherine Baicker, David Cutler & Zirui Song, *Workplace Wellness Programs Can Generate Savings*, 29 HEALTH AFF. (MILLWOOD) 304–11 (2010), <http://www.healthaffairs.org/doi/10.1377/hlthaff.2009.0626>; Michael D Parkinson et al., *UPMC MyHealth: Managing the Health and Costs of U.S. Healthcare Workers*, 47 AM. J. PREV. MED. 403–10 (2014), <https://linkinghub.elsevier.com/retrieve/pii/S0749379714001524>; Adrianno McIntyre et al., *The Dubious Empirical and Legal Foundations of Workplace Wellness Programs*, 27 HEAL. MATRIX J. LAW-MEDICINE 59–80 (2017).

100 JAMA. 2019 Apr 16; 321(15): 1462–1463.

101 Jean Marie Abraham, *Employer Wellness Programs—A Work in Progress*, 321 JAMA 1462–1463 (2019), <http://www.ncbi.nlm.nih.gov/pubmed/30990536>.

102 McIntyre et al., *supra* note 99; Herman, *supra* note 20.

103 Abraham, *supra* note 101 at 1463.

104 Natasha Singer, *On Campus, A Faculty Uprising Over Personal Data*, THE NEW YORK TIMES, September 14, 2013; Trotman, *supra* note 80; Andie Burjek, *Genetic Testing Gets Toothy as a Workplace Benefit*, WORKFORCE (2016), <https://www.workforce.com/2016/11/30/genetic-testing-gets-toothy-test-workplace-benefit/> (last visited Aug. 13, 2019); Tom Murphy, *Employers Try Adding Genetic Testing to Employee Wellness Mix*, INSURANCE JOURNAL (2015), <https://www.insurancejournal.com/news/national/2015/05/07/367043.htm> (last visited Aug. 13, 2019).

105 Singer, *supra* note 104.

should be returned to employers. In other words, because they collect sensitive health and genetic information on employees, there are privacy concerns about employer-based wellness programs. As some proposals to modify the regulations around wellness programs would weaken the privacy protections, ‘Congress may ultimately need to resolve the tension between its avid support for wellness programs and its efforts to stamp out disability discrimination.’¹⁰⁶

One key question about wellness programs is whether the programs still qualify as voluntary and are therefore compliant with ADA and GINA regulations, if financial incentives are offered. In 2016, the EEOC issued rules, under ADA and GINA, that permitted employers to increase premiums by up to 30 per cent of self-only coverage if employees opt out of employer-sponsored wellness programs that request ADA- or GINA-protected information.¹⁰⁷ However, these rules were vacated after being challenged in court.¹⁰⁸ The EEOC is expected to issue new rules on wellness program incentives in December 2019.¹⁰⁹

Although voluntariness is important, what is most concerning and relevant to this discussion is that some proposed laws on wellness programs would allow wellness programs to share employees’ individually identifiable genetic information with employers by exempting them from limitations on wellness programs outlined in ADA and GINA.¹¹⁰ If the privacy rules of wellness programs are relaxed, it’s not hard to imagine a future scenario in which an employer legally learns that an employee is at high genetic risk for developing a chronic disease. Although illegal under GINA, self-insuring employers would have financial reasons to discriminate against such an individual, even though the person’s health has nothing to do with his or her ability to do the job. If that person was laid off during a business slowdown, it would be difficult for the (former) employee to prove that they were the victim of discrimination. Indeed, employers may at some point argue that hiring such an individual poses an undue financial hardship. But no employer, regardless of size, should be able to deny opportunities to potential or current employees based on genetic information because of a concern about future healthcare costs.

106 McIntyre et al., *supra* note 99 at 78.

107 U.S. Equal Employment Opportunity Commission, EEOC ISSUES FINAL RULES ON EMPLOYER WELLNESS PROGRAMS (2016), <https://www.eeoc.gov/eeoc/newsroom/release/5-16-16.cfm>; U.S. Equal Employment Opportunity Commission, EEOC’S FINAL RULE ON EMPLOYER WELLNESS PROGRAMS AND TITLE I OF THE AMERICANS WITH DISABILITIES ACT, <https://www.eeoc.gov/laws/regulations/qanda-ada-wellness-final-rule.cfm> (last visited May 1, 2019); Jonathan E. O’Connell, *EEOC Wellness Regulations Vacated Effective JAN. 1, 2019*, SOCIETY FOR HUMAN RESOURCE MANAGEMENT (SHRM), 2018, <https://www.shrm.org/ResourcesAndTools/legal-and-compliance/employment-law/Pages/Court-Report-EEOC-wellness-regulations-vacated.aspx>; Allen Smith, *EEOC Ordered to Reconsider Wellness Rules*, SOCIETY FOR HUMAN RESOURCE MANAGEMENT (SHRM), 2017, <https://www.shrm.org/resourcesandtools/legal-and-compliance/employment-law/pages/aarp-eeoc-wellness-regulations.aspx>.

108 Jamie L. Leary, *Will the Framework of Laws That Govern Wellness Programs Change Once Again? Take Two Aspirin and Call Me After March*, NATIONAL LAW REVIEW, March 6, 2018, <https://www.natlawreview.com/article/will-framework-laws-govern-wellness-programs-change-once-again-take-two-aspirin-and>.

109 Katherine Kelton, EEOC INCENTIVE RULES UPDATE: WHAT IT MEANS FOR YOUR WELLNESS PROGRAM STAYWELL (2019), <https://www.staywell.com/insights/impending-eeoc-changes-mean-employer-well-programs>.

110 Kathy L Hudson & Karen Pollitz, *Undermining Genetic Privacy? Employee Wellness Programs and the Law*, 377 N. ENGL. J. MED. 1–3, 2 (2017), <http://www.nejm.org/doi/10.1056/NEJMp1705283>.

On March 2, 2017, the Preserving Employee Wellness Programs Act 2017 (HR 1313) was introduced but did not pass. It would allow employers to offer employees up to a 30 per cent health insurance discount for providing medical information to wellness programs and allow them to ask employees about their own or their family's medical history and genetic information or pay a surcharge.¹¹¹ Many patient advocacy groups and scholars expressed concerns that HR1313 would have weakened privacy protections offered by the ADA and GINA.¹¹² As of writing, this legislation has not passed, and since Democrats took control of the House in January 2019, passage of the bill is less of a concern. However, it's clear that regulations around employer-based wellness programs need clarification. As policies around wellness programs continue to develop, we must make sure that they do not weaken GINA's strong employee privacy protections.

CONCLUSION

As genetic testing proliferates and precision medicine matures and evolves, it is important to reevaluate the laws that protect consumers, patients, and research participants from genetic discrimination in employment and health insurance settings. In this paper, we reviewed the ethical arguments that make the case against genetic discrimination in employment and health insurance settings. We examined US policies that protect the privacy of identifiable health information and prohibit employment and health insurance discrimination based on genetic and health status. We establish that existing legislative protections fall short in many ways, fail to address emerging issues, and are under serious threat. We must safeguard and protect broad prohibitions against genetic and health discrimination in health insurance settings, and this includes preserving the privacy protections of genetic information in employment settings. Increasing accuracy and demonstration of relevance of genetic information may justify specific additional exceptions to GINA in employment settings, such as a 'direct threat' exception, but modifications to the law can only be made after rigorous societal debate, if at all. Employers should never be permitted to use genetic information to discriminate against employees because of a desire to reduce healthcare costs. The policies that protect against genetic and health-related discrimination in employment and insurance settings need attention, strengthening, and refinement in an environment in which predictive capabilities and healthcare costs both continue to increase. Otherwise, precision medicine will fail to live up to its promise.

111 Julia Belluz, *A New Bill Would Allow Employers to See Your Genetic Information—Unless You Pay a Fine*, VOX, March 13, 2017, <https://www.vox.com/policy-and-politics/2017/3/13/14907250/hr1313-bill-genetic-information>.

112 Reed Abelson, *How Healthy Are You? G.O.P. Bill Would Help Employers Find Out*, THE NEW YORK TIMES, March 10, 2017; American Society of Human Genetics, *ASHG OPPOSES H.R. 1313, THE PRESERVING EMPLOYEE WELLNESS PROGRAMS ACT (2017)*, https://www.eurekaalert.org/pub_releases/2017-03/asoh-aoh030817.php; National Organization for Rare Disorders, *NORD ISSUES STATEMENT OPPOSING THE PRESERVING EMPLOYEE WELLNESS PROGRAMS ACT (H.R. 1313) (2017)*, <https://rarediseases.org/nord-issues-statement-opposing-preserving-employee-wellness-programs-act-h-r-1313/>; Roberts, *supra* note 33.

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CONFLICT OF INTERESTS

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