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Is GINA Worth the Wait?

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It has been pending in Congress for twelve years, despite the support of the last two presidential Administrations and the National Institutes of Health. It has been the subject of extensive affirmative lobbying by academic medical centers, pharmaceutical and biotech companies, genetic disease advocacy groups, and civil rights organizations. It has overcome vehement objections by employers and insurers. Its final passage, however, has been thwarted by a few Congressional leaders, who have prevented enactment despite overwhelming bipartisan support in both houses of Congress.

Based on this legislative history, one could not help but assume that the Genetic Information Nondiscrimination Act (GINA)¹ is a revolutionary piece of legislation that, if finally enacted, would provide extensive, effective, and comprehensive protection against genetic discrimination in health insurance and employment. Unfortunately, such an assessment would be incorrect. Indeed, GINA may be a case of too much ado about too little. GINA is a fatally flawed bill, whose chances of achieving its noble goal of genetic nondiscrimination were doomed from the start by a health finance system in which individual health insurance is medically underwritten and by employment laws that fail to protect the privacy of employee health information.

This article puts GINA into perspective by reviewing the need for legislation, the bill's key provisions, and its likely consequences. The article also discusses the essential issues of discrimination and disclosure of genetic information in health insurance and employment that GINA does *not* address. It observes that the shortcomings of GINA stem from the health finance system of the United States and the absence of effective health privacy legislation. Upon closer inspection, discrimination based on “genetic information” is not a discrete and singular issue; it is a case study for the broader issue of the permissible uses and disclosures of predictive health information.

History of Genetic Nondiscrimination Laws

Health Insurance

Individual health insurance policies are medically underwritten on an individual basis. Health insurers consider the applicant's current health status and his or her likely future claims along with those of any dependents to be covered. Individual health insurance is regulated by the states. When the Human Genome Project officially began in 1990, the potential for genetic discrimination in health insurance was the first issue to receive the attention of scholars, policy analysts, and state legislatures. In 1993, the NIH/DOE Task Force on Genetic Information and Insurance issued a report recommending that “[i]nformation about past, present, or future health status, including genetic information, should not be used to deny health care coverage or services to anyone.”² State legislatures, often responding to intense lobbying efforts by consumer advocates and researchers, soon began enacting bans on genetic discrimination in individual health insurance. By the end of

2007, the overwhelming majority of states had enacted laws prohibiting genetic discrimination in health insurance.³

Group health policies are group underwritten. The claims experience of the group may affect renewability and rates, but individual risks are not considered and individuals are not treated differently in coverage or rates. Group health insurance is customarily issued through employer-sponsored group health plans, which may be either self-insured or commercially insured. Because group health plans are considered “employee welfare plans,” they are subject to the federal Employee Retirement Income Security Act (ERISA).⁴ As to these plans, state laws prohibiting genetic discrimination in health insurance are preempted. In 1996, Congress enacted the Health Insurance Portability and Accountability Act (HIPAA),⁵ which amended ERISA in several respects. A little discussed provision of HIPAA provides that neither group health plans nor health insurers offering group coverage may establish rules for eligibility of any individual or a dependent of the individual based on “genetic information.”⁶ This means that genetic discrimination in employer-sponsored group health insurance, by far the largest source of health coverage, is illegal under federal law.

Employment

The first state laws prohibiting genetic discrimination in employment were enacted in Florida,⁷ Louisiana,⁸ and North Carolina⁹ in the early 1970s. These laws prohibited discrimination on the basis of sickle cell trait. In 1981, New Jersey prohibited discrimination in employment based on the following genetic traits: sickle cell, hemoglobin C, thalassemia, Tay Sachs, or cystic fibrosis.¹⁰ These initial laws, prohibiting irrational discrimination against the unaffected carriers of recessive disorders, were followed by more comprehensive bans against discrimination on the basis of predictive genetic information. The laws typically prohibit employers from requiring or requesting a genetic test or using the results of a genetic test for a discriminatory purpose. The laws apply to all genetic disorders regardless of the mode of inheritance. By the end of 2007, approximately two-thirds of the states had enacted laws prohibiting genetic discrimination in employment.¹¹

At the federal level, Executive Order 13145 was issued in 2000.¹² It prohibits genetic discrimination in federal employment based on genetic information. The Order was intended to pave the way for legislation applicable to the private sector, but broader legal restrictions have not been enacted. The only other federal law relevant to genetic discrimination in employment is the Americans with Disabilities Act (ADA),¹³ which prohibits discrimination in employment on the basis of disability. In 1995, the Equal Employment Opportunity Commission issued a nonbinding interpretation that discrimination against individuals based on genetic predisposition was unlawful under the ADA. A subsequent series of Supreme Court cases,¹⁴ in which the Court adopted a narrow view of the coverage of the ADA, convinced virtually all commentators that the ADA would *not* apply to asymptomatic individuals who were discriminated against on the basis of genetically increased risk of disease.¹⁵

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Need for GINA

Proposals for state and federal legislation prohibiting genetic discrimination in health insurance and employment began by the mid-1990s,¹⁶ preceding any evidence of significant discriminatory conduct by health insurers or employers. The demands for federal legislation have intensified over the years, despite enactment of numerous state genetic

nondiscrimination laws and the continued absence of any significant evidence of discrimination.¹⁷ Why?

There is considerable evidence that numerous individuals who are genetically at-risk for some serious disorders decline potentially efficacious genetic testing and medical intervention because they are concerned about the possibility of discrimination against themselves and family members.¹⁸ The supposed need for such defensive practices has motivated genetic disease advocacy and civil rights groups to support nondiscrimination legislation. In addition, genetics researchers, biotech companies, pharmaceutical companies, and genetic test developers realize that their efforts will be for naught unless individuals are willing to undergo genetic testing. Thus, researchers and commercial interests have been among the staunchest supporters of genetic nondiscrimination legislation. Federal legislation has been generally viewed as preferable to state legislation because it would be more consistent and comprehensive than the patchwork of state laws, even though GINA would not preempt more protective state laws.

There are four main concerns regarding the use of genetic information in employment and health insurance that have driven consumer efforts to obtain genetic nondiscrimination legislation. The same concerns also apply to the use of genetic information in life, disability, and long-term care insurance. First, individuals are concerned about having their health privacy invaded by commercial entities searching their health records for the existence of genetic information. Second, individuals fear they will be required to undergo genetic testing as a condition of health insurance or employment and thereby to confront information about their health risks that they would prefer not to know. Third, individuals worry that a health insurer or employer will misunderstand the significance of the genetic information, resulting in their being erroneously disqualified from a job or insurance.

Finally, individuals are concerned that even if the information is not misinterpreted, the results will be used to exclude them from access to something of great importance to them and to which they believe they have a degree of entitlement.

Health Insurance Provisions

GINA provides that a health insurer offering health insurance coverage in the individual market may not establish rules for eligibility or adjust premium or contribution amounts of any individual based on genetic information. Genetic information is defined as information about an individual's genetic tests, the genetic tests of family members, or the occurrence of a disease in family members of the individual. Genetic information does not include information about the sex or age of an individual.

Health insurers also may not request or require an individual or a family member of the individual to undergo a genetic test. The same restrictions also apply to insurers offering Medicare supplemental policies. GINA further provides that group health insurers, which are prohibited by HIPAA from discriminating in coverage and premiums based on genetic information, are required to comply with the privacy and confidentiality rules of HIPAA and are barred from requesting or requiring genetic information about a participant, family member, beneficiary, or enrollee prior to enrollment.

The health insurance provisions of GINA are similar to state laws prohibiting genetic discrimination in health insurance, but the approach of all of these laws is fundamentally flawed. Under GINA, it would be unlawful for an individual health insurer to discriminate against an individual because the individual's genetic test or family history puts the individual at increased risk of developing a disease or disorder. To take a common example, it would prohibit discrimination against a woman who tested positive for one of the genetic

mutations associated with an increased risk of breast cancer. Nevertheless, after a period of time, assuming the woman developed breast cancer, GINA would provide no protection. GINA, like all of the state laws on the issue, would apply only to asymptomatic individuals. It would be a matter of state insurance law whether the insurer could decide not to renew the policy or to increase the rates substantially. Only a few states have guaranteed renewal laws.

This absence of protection for affected individuals is not a loophole or oversight. It is the essence of the problem, and its centrality is illustrated by any attempt to eliminate the problem. Thus, if Congress believed it to be unfair for a genetically predisposed woman who developed breast cancer to lose her health insurance, would it help for Congress to prohibit discrimination against women who are genetically predisposed to breast cancer as well as women who develop gene-influenced breast cancer? Such a law would protect the 5 to 10 percent of women who get breast cancer from known genetic causes, but it would not protect other women who get breast cancer from unknown causes. Would it help for Congress to enact legislation prohibiting discrimination against all women who are genetically predisposed to breast cancer or who develop breast cancer? What would be the moral basis for giving favorable treatment to women with breast cancer while permitting discrimination against all other women (and men) who have other types of cancer or other illnesses?

Perhaps the greatest risk posed by enacting GINA would be that lawmakers might become complacent and believe that the problem of genetic discrimination in health insurance and employment has been adequately addressed by the new federal law.

Genetic discrimination in health insurance is merely a symptom of the broader problem of the lack of distributive justice in an individual health insurance market based on individual medical underwriting. The problem cannot be solved by genetic nondiscrimination laws, but only by enacting laws requiring guaranteed issue, guaranteed renewal, community-rated individual health insurance, or some other form of health coverage that does not rely on individual underwriting.¹⁹ The issue will persist until Congress enacts legislation providing that sick people and those likely to get sick have a right to health care coverage.

Employment Provisions

GINA would make it an unlawful employment practice for an employer, employment agency, labor organization, or training program to refuse to hire or to discharge any applicant or employee, or otherwise to discriminate against any employee with respect to compensation, terms, conditions, or privileges of employment based on genetic information. The definition of genetic information is the same for employment as for health insurance, mentioned above.

GINA also would make it unlawful for an employer, employment agency, labor organization, or training program to request, require, or purchase genetic information about an employee. One key exception is that it would be permissible for an employer to undertake genetic monitoring of the biological effects of toxic substances in the workplace if: the employer provides written notice to the employee; the employee provides prior, knowing, voluntary, and written authorization, or the monitoring is required by law; the employee is informed of individual monitoring results; the monitoring is in compliance with any applicable federal or state laws; and the employer receives only aggregate information that does not identify individual employees.

Despite the seemingly comprehensive prohibition on employer acquisition of genetic information, it is likely that employers would continue to obtain genetic information on a routine basis. In accordance with section 102(d)(3) of the ADA,²⁰ after a conditional offer of

employment, employers are permitted to require, as a condition of employment, that individuals submit to a medical examination and sign an authorization for the release of their health records. There are no limits on the scope of the examination or the records disclosed, although conditional offers may be withdrawn for medical reasons only if the examination or records indicate that the individual, with or without reasonable accommodation, is unable to perform the essential functions of the job.

Each year in the United States, conditional offerees sign an estimated 10.2 million authorizations for release of their health records.²¹ Because of the increasing interoperability of electronic health record networks, health record disclosures are becoming more comprehensive. Even if GINA resulted in employers requesting that custodians of health records (e.g., health care providers) release only nongenetic health information, there is no practical way to do so, and the entities are likely to continue the practice of routinely sending all of an individual's records. Thus, the number one concern of individuals today, that employers have access to their genetic test results, would remain their number one concern even if GINA were enacted. Effective protection of genetic information in the employment setting requires a ban on employer requests for comprehensive records at the post-offer stage; the research, development, and adoption of health information technology to facilitate the disclosure of only job-related health information; and the legal requirement to limit the scope of disclosures to job-related information.²²

Genetic Exceptionalism

GINA, like numerous state genetic nondiscrimination laws, is based on an approach known as “genetic exceptionalism.”²³ This means that genetic information is treated separately and differently from other health information. To many observers and elected officials, the need for “genetic” nondiscrimination legislation has seemed self-evident to address what has been regarded as a “genetic” discrimination problem. For others, genetic exceptionalism represents poor public policy for the following reasons: (1) it is impossible to define “genetic” when scientists have identified that genes play a role in virtually every human health problem; (2) it is impossible to isolate genetic information in health records; (3) a general law is easier to apply than separate laws for various health conditions; (4) having a separate law for genetic information increases the stigma associated with genetic conditions; and (5) it is difficult to make a moral argument that it is impermissible to discriminate against people on the basis of genetic information but that it is permissible to do so if the condition is not genetic.²⁴

Although enacting a genetic-specific law, such as GINA, might be easier than enacting more sweeping reforms, there are drawbacks to following the most politically expedient path. Fears of genetic discrimination in individual health insurance cannot be resolved unless legislation is enacted giving individuals the right of access to health insurance or health care irrespective of their current or likely future health condition. Fears of genetic discrimination in employment cannot be allayed without enacting legislation limiting the ability of employers to access comprehensive health records of individuals applying for jobs. It is unclear whether GINA would be a catalyst to overcoming these larger problems or serve to delay the enactment of more meaningful reforms.²⁵

Conclusion

The main value of GINA is its symbolism. If enacted, federal law would declare a national policy against discrimination in health insurance and employment on the basis of genetic information. The symbolic value of many other forms of antidiscrimination laws has led to widespread changes in attitudes and actions by private parties. Enacting this legislation,

however, is not without risks. First, the law's genetic exceptionalism approach could serve to increase the stigma of genetic conditions, genetic tests, and genetic information. Second, individuals might be convinced by public pronouncements of the value of GINA and rely upon it to their detriment, such as by undergoing predictive genetic testing and subsequently having their test results released to future employers. Third, perhaps the greatest risk posed by enacting GINA would be that lawmakers might become complacent and believe that the problem of genetic discrimination in health insurance and employment has been adequately addressed by the new federal law.

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