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Eric A. Feldman

University of Pennsylvania Carey Law School

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The Genetic Information Nondiscrimination Act (GINA):
Public Policy and Medical Practice in the Age of Personalized Medicine

Eric A. Feldman, JD, Ph.D.
Professor of Law
Deputy Dean for International Affairs
University of Pennsylvania Law School
3400 Chestnut Street
Philadelphia PA 19104
215-573-6400-T
215-573-2025-F
efeldman@law.upenn.edu

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Abstract

Survey data suggest that many people fear genetic discrimination by health insurers or employers. In fact, such discrimination has not yet been a significant problem. This article examines the fear and reality of genetic discrimination in the United States, describes how Congress sought to prohibit such discrimination by passing the Genetic Information Nondiscrimination Act of 2008 (GINA), and explores the implications of GINA for general internists and their institutions. It concludes that medical providers and health care institutions must be familiar with the general intent and specific terms of GINA, and should continue to collect genetic information that can contribute to the high quality provision of medical treatment. Not doing so violates their medical mission and diminishes the quality of care patients deserve.

The Genetic Information Nondiscrimination Act (GINA):

Public Policy and Medical Practice in the Age of Personalized Medicine

As patients and general internists contemplate the advent of personalized medicine, collecting and managing genetic information has taken on increasing importance. Utilizing information about an individual's clinical, genetic, genomic, and environmental conditions, personalized medicine offers the possibility that internists will be able to predict which diseases are most likely to affect particular individuals, evaluate how those diseases will progress, and determine the most appropriate treatment regimen.¹ But the road to achieving those goals presents various challenges.² Although there are now a plethora of tests that can identify the existence of specific genes that confer increased risk of disease, for example, scientists do not yet have the ability to make accurate predictions about the likelihood that these genes will lead to particular diseases. In addition to the scientific challenges, there are a variety of unresolved policy questions. Among the most important revolve around questions of genetic discrimination—whether and to what extent the existence of genetic discrimination inhibits peoples' willingness to participate in research protocols involving genetic information and to avail themselves of genetic testing.³ This perspective examines the fear and reality of genetic discrimination, describes a recent effort by Congress to prohibit such discrimination, and discusses the implications of the new federal legislation for general internists and their institutions.

Although we know less than we should about why people forgo participation in clinical genetic research or why patients do not undergo genetic testing, survey data suggest that a significant number of people fear that they will suffer from genetic discrimination if they allow their genetic material to be sampled and analyzed.⁴ Such discrimination could be perpetrated by a health

insurer which learned that a patient tested positive for a gene associated with a certain type of cancer. Discrimination could also occur in the employment setting, with employers using information about an individual's genetic makeup to deny employment, raises, promotions, or other benefits. As noted by Senator Kennedy in a report of the Senate's Committee on Health, Education, Labor, and Pensions, "Fears about the possible misuse or unauthorized disclosure of genetic information appear to adversely impact the desire of individuals to participate in genetic research. Such fears also extend to clinical practice, discouraging both patients and providers from taking full advantage of genetic tests and technologies."⁵

In an effort to address such fears, a group of elected officials and policy advocates in the mid-1990s began to press for federal legislation prohibiting genetic discrimination.⁶ Thirteen years after legislation was first introduced, Congress approved the Genetic Information Nondiscrimination Act (GINA) in May 2008.⁷

GINA takes aim at two areas of potential discrimination, health insurance and employment. With regard to health insurance, GINA prohibits insurers from using genetic information to adjust group or individual premiums, deny coverage, or impose preexisting condition exclusions, and makes it illegal for them to require or request genetic testing or intentionally obtain genetic information. Controversially (and unfortunately), it does not cover the areas of life, disability, or long term care insurance. In the employment context, GINA prohibits employers with 15 or more employees from willfully acquiring genetic information or using it to make decisions about hiring, compensation, and other conditions of employment. Importantly, GINA does not prohibit insurers or employers from taking into account manifested medical conditions (many of which

may have a genetic basis) when pricing insurance or making employment decisions. One significant shortcoming of GINA is that by prohibiting insurers and employers from accessing genetic information (including family medical history), they could begin to overemphasize the importance of existing physical conditions, manifested diseases, and lifestyle risks like smoking and obesity when assessing individual health status.⁸ Sharply distinguishing between genetic information and other types of information will result in exactly the type of discrimination *vis a vis* insurance premiums and employment opportunities that GINA is meant to prevent.⁹

Because GINA was passed almost two years before the Patient Protection and Affordable Care Act of 2010 (PPACA), one might assume that many of its most important provisions were superseded by the new health reform legislation.¹⁰ In fact, PPACA does little to alter GINA's approach to genetic discrimination. Perhaps most important, the much publicized preexisting condition exclusion does not affect genetic information, since under PPACA such information is not considered a preexisting condition.¹¹ In addition, although PPACA prohibits denial of coverage based on genetic information GINA is significantly more stringent, prohibiting insurers from collecting such information or using it to set premiums. The employer-related provisions of GINA are untouched by the new health care bill.

GINA enjoyed overwhelming Congressional support—it passed 94-0 in the Senate and 414-1 in the House—despite its novelty. Most antidiscrimination legislation addresses patterns of past discrimination.¹² GINA, however, is meant to prevent genetic discrimination from occurring in the future, since there is only limited evidence that it is currently a problem.¹³

The strongest evidence that genetic discrimination is a significant concern comes from the early 1970s, when some state governments mandated genetic testing of African-Americans to identify both carriers of and those suffering from sickle cell anemia. The states sought to justify testing by arguing that carriers of the sickle cell gene could be hyper-susceptible to certain workplace toxins.¹⁴ The discrimination by both health insurers and employers that resulted from screening for sickle cell anemia was addressed by Congress in 1972 by the National Sickle Cell Anemia Control Act, which withheld federal funds from states that mandated sickle cell testing.¹⁵

In addition to the history of sickle cell screening, supporters of GINA invoked anecdotal evidence of isolated instances of genetic discrimination to argue that GINA was necessary. One sponsor of GINA underscored the Congressional testimony of a mother who claimed that a large health insurance company had denied coverage for her two children because they were carriers of the gene for alpha-1 antitrypsin deficiency.¹⁶ With regard to employment, GINA's proponents pointed to surveys like the American Management Association's "Workplace Testing Survey," which uncovered several instances of members using what they understood to be genetic information in hiring and firing decisions.¹⁷ Likewise, the Office of Technology Assessment conducted a survey in 1989 of Fortune 500 companies, with 12 of 330 respondent companies admitting that they conducted genetic tests of employees.¹⁸

Given the weak evidence that health insurers and employers were engaging in genetic discrimination, GINA's proponents sought to emphasize the need to prevent future discrimination. They pointed to the millions of people affected by genetic disorders, concluding that genetic discrimination *could* affect everyone. Moreover, supporters of GINA argued that

regardless of whether there is currently widespread genetic discrimination, fear of discrimination could dampen research efforts. This was emphasized by the Senate Committee on Health, Education, Labor, and Pensions, which published a report on genetic discrimination in 2007 finding that fear of discrimination is the most common reason for not participating in research on potentially lifesaving genetic testing.¹⁹

Proactive legislation may appear more appealing than reacting, often too late, when serious social problems arise. But in the case of genetic discrimination, both state and the federal governments already offered potential litigants a variety of legal tools with which to protect themselves. On the state level, almost all states have laws limiting the ability of health insurers to use genetic information, and more than two-thirds have laws banning most forms of genetic discrimination in the workplace.²⁰ A number of federal laws, most importantly the Health Insurance Portability and Accountability Act, the Americans with Disabilities Act, and Title VII of the Civil Rights Act, also enable aggrieved individuals to litigate their claims. Given that robust legal foundation, it is questionable whether GINA adds any real legal protection for those who believe they have been victims of genetic discrimination. So far, only eight reported cases have mentioned GINA since its enactment in 2008; none of them involved health insurers, and none escaped dismissal.²¹ Over time the situation could change. But so far, GINA has not been a factor in legal disputes involving genetic discrimination.

For general internists and other physicians who necessarily collect information about their patients' health and might in appropriate circumstances suggest genetic testing, GINA presents a number of questions. Because GINA defines genetic information to include family medical

history, many if not all medical records contain information that is, at least under GINA, potentially discriminatory. As a result, general internists and medical institutions are likely to be a conduit for the flow of genetic information to insurance companies and employers that could be used in an unfair, discriminatory manner. Under GINA, they are unlikely to be exposed to legal liability. But GINA does raise a number of ethical and practical concerns about whether, and how, genetic information should be maintained in patient medical records.

The least desirable outcome of GINA on medical practice would be for providers to avoid collecting genetic information because they fear being dragged into a genetic discrimination lawsuit. It is apparent that genetic information is essential to good medical practice—asking patients about family medical history, for example, and advising some pregnant women to seek genetic testing and counseling, is essential. In some circumstances, genetic testing is critical to protecting the health of workers who could unduly suffer from certain types of occupational exposure. Participating in wellness programs is a similarly important activity. Clearly such practices should not change. Although in most circumstances GINA prohibits employers and insurance companies from requiring or recommending genetic tests, it explicitly makes an exception for health care professionals providing health care services, including those involved in wellness programs. Under the terms and enforcement provisions of GINA, there is no indication that physicians who recommend genetic testing in such contexts are at risk by continuing their activities.

Maintaining medical records that include genetic information raises additional questions.²² A 1994 section of the American Medical Association's Code of Medical Ethics suggests that

physicians should sometimes maintain separate records for genetic information so that they do not provide such information to insurance companies.²³ When genetic information is excluded from a patient's main medical record, the AMA advises physicians to inform insurance companies (and presumably other entities like employers) that genetic information is being withheld.²⁴ Likewise, regulations accompanying GINA advise insurance companies and employers to make clear in their requests for medical information that they do not wish to receive any genetic information.²⁵ Maintaining a separate record for genetic information is likely to impose an added burden on providers. Doing so may be the most ethically appropriate practice, since it will reduce the likelihood that insurers and employers will obtain genetic information, and the corresponding possibility that they will use it to discriminate. But in reality the incentive for providers to take on this burden is quite weak, since bundling all patient information in a single medical record appears to have few adverse legal consequences.

As we flirt with the possibilities offered by personalized medicine, it is critical that we continue to respect patient privacy by carefully managing all health-related information. Genetic information is particularly sensitive, since it has the potential to be misused by insurers, employers and others in unfairly discriminatory ways. Happily, it does not appear that genetic discrimination has so far been a significant problem in the United States. Still, Congress chose to enact GINA in 2008, largely to address the public's fears of genetic discrimination. Medical providers and health care institutions have an ethical obligation to be familiar with the general intent and specific terms of the legislation. Perhaps more importantly, they must continue to collect all information, including genetic information, which can contribute to the high quality

provision of medical treatment. Not doing so violates their medical mission and diminishes the quality of care patients deserve.

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Conflicts of Interests

The author has no conflicts of interest.

¹ Regulations Under the Genetic Information Nondiscrimination Act of 2008, 75 Fed. Reg. 68912 (2010).

² Haga SB, Carrig MM, O'Daniel JM et al. Genomic risk profiling: Attitudes and use in personal and clinical care of primary care physicians who offer risk profiling. *J Gen Intern Med.* 2011; 26:834-40.

³ Hudson KL, Holohan MK, Collins FS. Keeping pace with the times — The Genetic Information Nondiscrimination Act of 2008. *N Engl J Med.* 2008; 358:2661-63.

⁴ *Protecting Workers from Genetic Discrimination: Hearing Before the Subcommittee on Health, Employment, Labor, and Pensions, Committee on Education and Labor, U.S. House of Representatives, 110th Cong., 1st Sess. 33-35 (2007) (prepared statement of Dean Karen Rothenberg).*

⁵ S.Rep.No.110-48, 110th Cong., 1st Sess. 6 (2007).

⁶ They appear to have had significant public support. “Besides the more than 200 health advocacy and business organizations that support this bill, recent surveys show 93 percent of Americans believe that employers and insurers should not be able to use genetic information to discriminate.” 153 Cong. Rec. 10310, 10323 (permanent ed. Apr. 25 2007) (statement of Rep. Biggert).

⁷ Genetic Information Nondiscrimination Act of 2008 , Pub.L. 110-233, 122 Stat. 881 (2008).

⁸ Korobkin R, Rajkumar R. The Genetic Information Nondiscrimination Act — A half-step toward risk sharing. *N Engl J Med.* 2008; 359:335-37.

⁹ For a European example, see Hoyweghen IV, Horstman K.. European practices of genetic information and insurance: Lessons for the Genetic Information Nondiscrimination Act. *JAMA.* 2008; 300:326-27.

¹⁰ Patient Protection and Affordable Care Act, Pub.L. 111-148, 124 Stat. 119 (2010).

¹¹ 42 U.S.C.A. §300gg-3(b)(1)(B) (2010) (“Genetic information shall not be treated as a condition described in subsection (a)(1) of this section in the absence of a diagnosis of the condition related to such information”). Like many parts of PPACA, the preexisting condition exclusion is undergoing legal review.

¹² Roberts JL. Preempting discrimination: Lessons from the Genetic Information Nondiscrimination Act. *Vanderbilt Law Rev.* 2010; 63:439-90.

¹³ This view is strongly stated by Senator Kennedy in S.Rep.No.110-48, 110th Cong., 1st Sess. 7 (2007): “Although surveys and polls demonstrate a fairly widespread fear of discrimination, there is little evidence or documentation of actual discrimination in health insurance.”

¹⁴ Kaufmann MB. Genetic discrimination in the workplace: An overview of existing protections. *Loyola Univ Chicago Law J* 1999; 30:393-438, 402–03.

¹⁵ *Ibid.*

¹⁶ *The Genetic Information Nondiscrimination Act: Hearing Before the Subcommittee on Health of the Committee on Energy and Commerce, U.S. House of Representatives*, 110th Cong., 1st Sess. 33 (2007) (prepared statement of Sharon Terry, Chair, Coalition for Genetic Fairness, and President, Chief Executive Officer, Genetic Alliance, Washington, DC). *Id.* at 4095. Correct cite??

¹⁷ S.Rep.No.110-48, 110th Cong., 1st Sess. 6 (2007).

¹⁸ S.Rep.No.110-48, 110th Cong., 1st Sess. 7 (2007).

¹⁹ S.Rep.No.110-48, 110th Cong., 1st Sess. 6-8 (2007). According to the report, 63% of respondents to a national telephone survey indicated that they would refuse genetic tests if health insurers or employers could gain access to the results, and 68% of patients answering a questionnaire said that fear of discrimination would keep them from billing their health insurance companies for genetic tests. For similar reasons, the AMA welcomed the passage of GINA, stating that “This new law will allow patients to take advantage of scientific advances in genetics, such as screenings and therapies, without worrying that their personal health information could be used against them by insurers or employers” (statement by Edward Langston, AMA Board Chair: AMA applauds passage of new law to protect patients from genetic discrimination [Internet]. Sussex: UK: Medical News Today; c2011 [posted 2008 May 23; cited 2011 Sep 16]. Available from:

2008<http://www.medicalnewstoday.com/releases/108633.php>). It also appears that many people are unaware of the existence of genetic testing (Baer HJ, Brawarsky P, Murray MF, Haas JS. Familial risk of cancer and knowledge and use of genetic testing. *J Gen Intern Med.* 2010; 25:717–24).

²⁰ Genetics and health insurance state anti-discrimination laws [Internet]. Washington: Denver (CO): National Conference of State Legislatures; c2011 [updated 2008 Jan; cited 2011 Sep 16]. Available from: <http://www.ncsl.org/default.aspx?tabid=14374>. Genetic employment laws [Internet]. Washington: Denver (CO): National Conference of State Legislatures; c2011 [updated 2008 Jan; cited 2011 Sep 16]. Available from: <http://www.ncsl.org/default.aspx?tabid=14280>.

²¹ See *Bullock v. Spherion*, No. 3:10-cv-465, 2011 WL 1869933 (W.D.N.C. May 16, 2011); *Robinson v. Starplex/CMS Event Security*, No. CV-10-723-HU, 2011 WL 1541290 (D. Or. Mar. 15, 2011); *Citron v. Niche Media/Ocean Drive Magazine*, No. 10-24014-CIV, 2011 WL 381939 (S.D. Fla. Feb. 2, 2011); *Benoit v. Pennsylvania Board of Probation and Parole-West Division*, No. 094047, 2010 WL 481021 (E.D. Pa. Feb. 9, 2010); *Capulong v. Dep’t of Education of*

Guam, No. 10-00005, 2011 WL 1134986 (D. Guam Mar. 24, 2011); Armes v. CSX Transportation, Inc., No. CCB-11-112, 2011 WL 2471476 (D. Md. June 20, 2011).

²² Klitzman R. Exclusion of genetic information from the medical record. JAMA. 2010; 304:1120-21.

²³ AMA code of ethics: Opinion 2.135 - insurance companies and genetic information [Internet]. Chicago (IL): American Medical Association; c2011 [updated 1996 June; cited 2011 Sep 16]. Available at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2135.page?>

²⁴ Ibid.

²⁵ See, for example: Regulations Under the Genetic Information Nondiscrimination Act of 2008, 75 Fed. Reg. 68912 (2010).