Commentary

Two cheers for GINA?

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Abstract

The Genetic Information Nondiscrimination Act of 2008 (GINA) was recently enacted in the United States. Its supporters have applauded the passage of GINA, and they hope that it will alleviate public fear about genetic discrimination and facilitate genetic testing and participation in genetic research. Critics worry that GINA does not provide adequate protection because it fails to address discrimination on the basis of non-genetic health-related information, and it only regulates the use of genetic information in health insurance and employment. Despite these limitations, GINA represents a major step forward in US policy. Additional research is needed to assess the impact of GINA on industry practice and public opinion. In the mean time, education about GINA and its limitations can help individuals make more informed decisions about genetic testing and participation in genetic research.

The Genetic Information Nondiscrimination Act of 2008 (GINA) was signed into US federal law on 21 May 2008 and will become effective within 12-18 months [1]. The first genetic nondiscrimination bill was introduced in the US House of Representatives in 1995. It took 13 years of lobbying from patient advocacy groups, researchers, medical professional organizations, and commercial interests to achieve bipartisan support for this type of legislation. Although many US states have laws that protect against genetic discrimination [2] and there are some limitations to the use of genetic information imposed on group health plans by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), advances in genetic research have created an urgency to the passage of more comprehensive federal legislation. For many, GINA "marks the beginning of a new era in health care" in which "[i]ndividuals no longer have to worry about being discriminated against on the basis of their genetic information" [3].

GINA was designed to protect individuals from discrimination on the basis of genetic information with respect to health insurance and employment. Specifically, it prohibits group and individual health insurers from collecting and using a person's genetic information in determining eligibility and premiums, and it limits employers' ability to collect genetic information and prohibits them from using such information in making employment decisions such as hiring, firing, job assignments, or any other terms of employment [1]. Genetic information is defined broadly under GINA and includes information about genetic tests on individuals and their family members as well as information about family medical history (the manifestation of a disease or disorder in family members, including dependents and first, second, third, and fourth degree relatives). A genetic test refers to an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. Supporters of GINA have applauded its passage into law and hope that it will alleviate the public's concerns about genetic discrimination [4-6], which many believe have discouraged the utilization of medically necessary genetic services and participation in important genetic research [7,8]. Some argue that this fear is not warranted, citing a lack of documented evidence of discriminatory practices [9]. Yet, individuals report experience with genetic discrimination that has a negative impact on them and their families [10,11], and recent historical examples include mandated screening for sickle cell anemia among African Americans [1].

Concerns about genetic discrimination, which are not unique to the United States, have led to the enactment of genetic nondiscrimination legislation in many European countries. Against a backdrop of relatively uniform general laws protecting the privacy of personal data, these genetics-focused laws vary considerably from country to country. In terms of defining genetic information, most of these laws are less inclusive than GINA in that they tend to leave family history outside the scope of legal protection [12,13]. In a recent article [14], Van Hoyweghen and Horstman argue that, overall, this legislation has been less effective than hoped in preventing the misuse of genetic information and allaying public concerns about genetic discrimination, and it may have the unintended effect of increasing other kinds of discrimination. The impact of GINA on industry practice and public opinion in the United States deserves careful examination and should be a research priority.

Critics assert that GINA is not an optimal policy response to the concerns it seeks to address because it is not comprehensive, in two senses. In the first sense, GINA is not comprehensive because it does not regulate health insurers' and employers' access to and use of all health-related information, or even all predictive information (that is, information with possible relevance to future health states). Someone considering genetic counseling or testing for the *BRCA1* breast cancer associated gene can be assured that, after GINA takes effect, their prospects for health insurance or employment will not be affected. No such assurance can be extended to an individual considering consultation with a mental health professional or a check of lipid levels. One aspect of justice is treating similar cases alike. In this respect, federal law seems to fall short, another instance of 'genetic exceptionalism' [15].

The necessity of defining and isolating genetic information from other kinds of information so that it can receive exceptional treatment introduces a new problem. As the scientific case builds for a multifactorial understanding of most diseases, and as information that has some claim to being genetic becomes integrated into routine care, any lines drawn may seem increasingly arbitrary [16,17]. For example, commentators have expressed some confidence that cholesterol tests would not be covered by GINA [18]. Yet one might assert, not entirely implausibly, that testing to determine low density lipoprotein (LDL) levels in someone suspected of having familial hypercholesterolemia is a genetic test. GINA provides broad protections for information about genetic susceptibilities to disease, but it does not protect information about manifestations of a disease or disorder in the individual [1]. The response could therefore be that high levels of LDL in such an individual would count as the manifestation of a disease or disorder, even in the absence of any evidence of atherosclerosis, and so any claim to protection under GINA would be lost for that reason. This serves to highlight another problem of where the line is drawn: what counts as a manifestation of a disease or disorder?

In the United States, the question of GINA and justice is tied to an underlying problem: the coupling of a widely held belief that individuals should have access to health care (regardless of health status and risk, at least to the extent that those factors are not wholly under their control) and employment (to the extent they are able to do a job) with a system in which access to health care is by no means guaranteed and in which medical underwriting in health insurance has implications for employment. Because employers are often providers of health insurance and face medical underwriting at the level of the whole company, they have reason to care about employee health for a reason that has nothing to do with job performance. For small employers, in particular, an employee with the potential to generate high health-care costs is a threat to the welfare of the enterprise. GINA reflects rather than solves this problem. It defines genetic information in order to make it off limits to health insurers and employers, preserving access to health-care and employment opportunities that would otherwise be imperiled by the general practice of medical underwriting; but it leaves that practice otherwise unaffected and, at the point of actual illness, removes any protection from the harsh effects of the current regime. Some may fear that the passage of GINA will serve as an escape valve, lessening pressure for broader health-care reform [19], but it could also be described as a step in the right direction.

The second sense in which GINA is not comprehensive is that it fails to address fears about genetic information and access to other kinds of opportunities or insurance products, including life, disability, long-term care, and mortgage insurance [20]. Policy issues related to life insurance and disability insurance have been studied at length, and in each area there are complexities that defy a simple 'one size fits all' solution [21,22]. European countries, less preoccupied with private health insurance, are ahead of the US in adopting nuanced regulatory approaches to other kinds of insurance, for example protecting access to policies in standard amounts and creating public entities to assess the actuarial validity of genetic tests [12,13]. If significant sections of the public focus on these gaps in US policy, reluctant to enter the genomic era without a blanket guarantee against harm, GINA may fail to live up to the hopes of its supporters.

Despite these limitations, the passage of GINA is a major step forward in US policy. For the advocates who have worked tirelessly for many years to pass GINA and for the patients, clinicians, and researchers who anticipate its benefits, this is a time to celebrate, not dwell on shortcomings. At last US citizens have a floor of protection across all states and across all categories of core genetic information, including family history.

The effect that this has on clinical practice, if any, remains to be seen. Clinicians may be more comfortable offering genetic testing, knowing that the results cannot be used for employment decisions or to determine eligibility or premiums in health insurance. Building on GINA, clinicians and researchers have an opportunity to improve their counseling of patients and potential research subjects. Given the patchwork of protections that existed before the passage of GINA, it would have been excusable to resort to a kind of warning like that given by police to criminal suspects that any information that results from this encounter/test/study may be used against you. It now becomes possible to inform patients and subjects that all health insurers and the vast majority of employers in the US will be prohibited from engaging in certain actions - thereby opening the door to tailored exploration of the areas of risk that remain (that is, the types of health-related information and opportunities or insurance products that are not covered under GINA). If we do our part in educating about GINA, individuals will be able to make more informed decisions about genetic testing and participation in genetic research.

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