

EDITORIAL

GINA, GENISM, AND CIVIL RIGHTS

Culminating its 13-year legislative gestation, The Genetic Information Nondiscrimination Act (GINA), was signed by President George W. Bush on May 21, 2008. GINA is the first major federal law to come out of the Ethical, Legal and Social Implications (ELSI) portion of the Human Genome Project. The passage of GINA has been widely celebrated. For the genetic research community, the act was sought to encourage people to become research subjects by providing them with some assurance that genetic research results would not be used against them by health insurance companies or employers. For Francis Collins, the project's leader, the long gestation period was a 'silver lining' in that it provided many opportunities 'to educate policymakers about the potential of genomic medicine and the challenges that must be addressed if we are to realize that potential'.¹

In the Rear and Limping a Little?

With our confusing public-private patchwork of health insurance, and 40 to 50 million Americans with no health insurance at all, Americans worry a lot about obtaining, paying for, and keeping their health insurance. Current law protects those who get group insurance from discrimination. But those in the market for individual policies worry especially about being discriminated against by being denied coverage because of 'pre-existing conditions,' and may see a genetic trait as something that can be used against them. Their health insurer could deny coverage or charge more; their boss could fire them. And, of course, loss of employment can lead directly to loss of employer-provided health insurance. Primarily because of the expense of genetic testing and the ambiguous meaning of most genetic tests, the reality of genetic discrimination has been less than the fear of it. That GINA was enacted prior to many cases of documented genetic discrimination makes it an exception to the famous

¹ K. Hudson, M.K. Holohan & Francis Collins. Keeping Pace with the Times – the Genetic Information Nondiscrimination Act of 2008. *New England J Med* 2008; 358: 2661–2663.

phrase of an Australian judge who observed, 'Law marches with science, but in the rear and limping a little.' In this unusual case, law has been enacted before new medical technology has caused any major problems.

GINA

The centerpiece of GINA lies in its broad definitions of genetic information and genetic test. *Genetic information* includes information about an individual or a family member's genetic tests, information about manifestation of a disease in a family member, information about receipt of genetic services and information about participation in clinical research that involves genetic services. Family members include an individual's dependents and first, second, third or fourth degree relatives. Group health plans and health insurers are prohibited from collecting genetic information for underwriting purposes, such as determining eligibility for benefits or setting premiums or employee contribution levels. They are also prohibited from requesting or requiring that an individual or a family member undergo a genetic test.

A *genetic test* refers to any analysis that detects genotypes, genetic mutations or chromosomal changes. It does not include an analysis of proteins or metabolites that is directly related to a manifested disease. Consequently, it does not change the rules on how group health plans and insurers acquire or use information about an enrollee's history of genetic or any other type of illness. Nor does it prevent the insurance company from increasing an employer's premium based on the manifestation of a disease of an employee already enrolled in the plan. As an example, GINA protects a woman who has had a genetic test that reveals that she has a BRAC1 or a BRAC2 mutation, as long as she does not have breast cancer. Once she has breast cancer, she is no longer protected by the act, whether or not her disease was genetically caused. The Act also does not cover other types of insurance, such as long-term care insurance and disability insurance. The long-term care industry has, so far successfully, argued that permitting individuals to get predictive genetic testing, like APOE testing, and then letting

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them use that information to decide whether to purchase long-term care insurance without disclosing the results, could put the insurers out of business.²

The Act places restrictions on the collection and uses of genetic information in employment by generally prohibiting employers from requesting or requiring genetic information of an employee or a family member. Exceptions include the inadvertent acquisition of medical history information, voluntary employer-sponsored wellness programs and health services, and genetic monitoring programs required by state or federal law to track the biological effects of toxins in the workplace. Like virtually all federal laws, this one will require extensive federal regulations, yet to be written, to spell out how it will work in practice. Employment rules are set to go into effect in October, 2009 and health insurance rules will not be fully in effect until January, 2010.

Racism, Sexism and Genism

Senator Judd Gregg has termed GINA ‘the first civil rights bill of the 21st Century,’ a phrase often quoted by the Senate’s main sponsor of the bill, Senator Olympia Snow and others, and endorsed by the American Civil Liberties Union as well. There are some similarities between racism and what one of us (GJA) has termed ‘genism.’ It has been suggested, for example, that concentration on the small portion of the genome that makes individuals different from others could encourage racism to be ‘replaced or supplemented by genism.’³ GINA, however, provides narrower protections than existing civil rights laws that prohibit discrimination on the basis of race, or even laws that prohibit discrimination on the basis of sex because it applies only to health insurance and employment discrimination. In this respect it is more like the federal Emergency Medical Treatment and Active Labor Act (EMTALA), which prohibits discrimination in hospital emergency departments based on inability to pay.

Discrimination based on genetics by health insurers and employers is important. But because of the mystique of genetics, the personal reactions to genetic information by individuals themselves, family members, and friends may be even more important. This is because genetic information can radically alter an individual’s perception

of themselves and their life’s prospects, as well as alter how they are perceived by their family members and friends. This helps us see that the broader policy issue in the new genetics is privacy, an issue tangential to GINA.

Genetic Privacy

Genetic discrimination, or genism, becomes possible (unlike discrimination based on race or gender) only after a genetic test has been performed and genetic information has been made available to another person or entity. The American public realizes this and a *ChangeWave* survey of 550 Americans, done one month after GINA was passed, concluded that ‘privacy issues remain a barrier to use of new genetic tests’ despite the passing of this law. Specifically, when asked about whether they would now be willing to share their genetic test results with others, 72% would share with a spouse, 71% with their physician, and 22% would share with a research institution. But only 3% would share with their health insurer, 2% with their current employer, and only 1% with a perspective employer.⁴ GINA of course is directed at employers and insurers, and Americans distrust them the most. But to the extent that genetic researchers thought the law would encourage more Americans to become research subjects, this early survey indicates that these hopes may go unfulfilled.

There is nothing quite like the DNA molecule as a source of predictive information about an individual. Collection and storage of identifiable DNA samples therefore presents the possibility, if not the probability, of unauthorized snooping into another’s ‘future diary.’⁵ The HIPAA privacy protections that apply to ‘covered entities’ holding medical information do apply to genetic information; but offer no protection at all to the DNA sample itself – which can reasonably be seen as a medical record in its own right.

An act designed to protect genetic privacy would focus on the major actions needed before genetic discrimination is even possible: the collection of DNA samples, the testing of DNA samples, the storage of DNA samples, and the rules regarding the sharing of results of DNA testing. As we suggested in a 1995 ELSI report, a genetic privacy act would forbid the taking of a DNA sample for

² C.D. Zick et al. Genetic Testing for Alzheimer’s Disease and its Impact on Insurance Purchasing Behavior. *Health Affairs* 2005; 24: 483–490; and R.J. Pokorski. Insurance Underwriting in the Genetic Era. *Am J Human Genetics* 1997; 60: 205–216.

³ G.J. Annas. Reforming Informed Consent to Genetic Research. *JAMA* 2001; 286: 2326–2328.

⁴ Burrill & Company. *ChangeWave Research, Personalized Medicine and Wellness Survey*. May 2008 (survey of 550 ‘upscale business professionals’). Available at http://www.burrillandco.com/content/CWSurvey_61708.pdf30 [accessed 8 July 2008].

⁵ G.J. Annas. Privacy Rules for DNA Databanks: Protecting Coded ‘Future Diaries’. *JAMA* 1993; 270: 2346–2350; and L. Glantz, P. Roche & G. Annas. Rules for Donations to Tissue Banks – What Next? *New England J Med* 2008; 358: 298–303.

the purpose of doing a genetic test without the individual's informed consent, would require that consent for genetic testing and the sharing of any test results be specific, and would prohibit the storage of identifiable DNA samples without authorization.⁶ (6)

Personal Genomics

GINA contains prohibitions against health insurers and employers who might seek to exert influence over the decisions of individuals to discover or use personal genetic information. Much more important are questions posed by the personal, voluntary uses facilitated by the new companies that promote direct to consumer genome-wide screening, such as 23andMe, Navigenics, and

⁶ G.J. Annas, L.H. Glantz & P. Roche. 1995. *The Genetic Privacy Act and Commentary*. Boston University School of Public Health: Boston, MA. Available at http://www.ornl.gov/sci/techresources/Human_Genome/resource/privacy/privacy1.html [accessed 8 July 2008].

DeCodeMe. Many Americans believe that privacy is dead or dying, especially in the age of Google, Facebook, and FISA, and Oprah. And to some extent it is true that once information is created, its use cannot be controlled, and misuse cannot be entirely prevented. Nonetheless, we believe that in our digital age, in which information is virtually indestructible, explicit ways to try to protect privacy are more, not less, critical. We believe people should, for example, be able to have their entire genome (or parts of it) screened if they want to, with the reasonable expectation that no one will have access to any of the results without their explicit authorization. Unless and until this is true, the promise of genetic screening will not be realized because, for most people, fear of exposure will outweigh any potential benefits.

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