

The Genetic Information Nondiscrimination Act

By Larissa C. Dean
and Eric E. Kinder

New regulations are on the way, and in the interim defense counsel should advise their employer clients to take the steps necessary to ensure compliance with GINA.

A Map for Navigating 2008's GINA Prohibitions

While most employers, and probably many employment lawyers, were unaware, a 13-year effort to regulate genetic testing and the use of genetic testing results came to fruition when President George W. Bush signed

the Genetic Information Nondiscrimination Act of 2008 (GINA or the act) on May 21, 2008. According to its supporters, GINA was “the culmination of a systematic, bipartisan effort to prohibit improper use of genetic information in workforce and insurance decisions.” *Protecting Workers from Genetic Discrimination: Hearing Before the H. Subcomm. on Health, Empl., Lab. and Pensions of the H. Comm. on Educ. and Lab.*, 110th Cong. (2007) (statement of Rep. Slaughter, member, House Comm. on Education and Labor). The act prohibits discrimination in employment and in the provision of health insurance benefits based on genetic tests and information. The employment provisions take effect on November 21, 2009, and the health insurance provisions take effect even sooner—May 21, 2009.

Personal Health Information and Employment

The impetus to enact genetic nondiscrim-

ination legislation began on the state level specifically to protect job applicants from discrimination based on potential susceptibility to sickle cell anemia. *National Conference of State Legislatures, State Genetics Employment Laws*, <http://www.ncsl.org/programs/health/genetics/ndiscrim.htm> (accessed Jan. 27, 2009). By January 2008, 35 states had enacted legislation prohibiting genetic discrimination in employment, although only 14 of those laws provided specific penalties for genetic discrimination in the workplace. *Id.* The first efforts to enact a federal genetic non-discrimination statute began in 1995. Supporters of such federal legislation sought to address documented instances of employers seeking to obtain genetic information and making employment decisions based on that information. In one instance, an employer conducted undisclosed screening for Carpal Tunnel Syndrome in an apparent attempt to find a genetic predisposition to the syndrome



■ Larissa C. Dean and Eric E. Kinder are members of Spilman Thomas & Battle in the firm's Charleston and Morgantown, West Virginia, offices, respectively. Both are members of DRI's Employment Law Committee and both focus on labor and employment law, including employee benefits, ERISA litigation, employment discrimination suits, drafting and reviewing of employment policies, administration of collective bargaining agreements and union organizing and a variety of employment-related litigation. Mr. Kinder is also the co-editor of *The Job Description*, the newsletter for DRI's Employment Law Committee.

to defend against workers' compensation claims. *National Partnership for Women & Families on behalf of the Coalition for Genetic Fairness, Faces of Genetic Discrimination: How Genetic Discrimination Affects Real People*, at 5 (2004). In one case cited in GINA's congressional findings, an employer conducted pre-employment health screenings that included undisclosed genetic testing of African Americans for sickle cell anemia, in addition to undisclosed testing of all individuals for syphilis and testing of females for pregnancy. *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9th Cir. 1998).

Further, rapid scientific advances in genetic testing have resulted in the increased availability of genetic tests for a greater number of genetic traits. The Human Genome Project reports the availability of 1,000 genetic tests that can be used for carrier screening, prenatal and newborn testing, presymptomatic testing for diseases, such as Huntington's and Alzheimer's diseases, and conformational diagnoses. *Department of Energy Human Genome Project Information, Gene Testing*, http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetest.shtml (accessed Jan. 28, 2009). Supporters of GINA cautioned that individuals would not avail themselves of the benefits genetic testing and services provide or participate in clinical trials unless they received protection against abuse of the information in the workplace. 154 CONG. REC. E818-03 (daily ed. May 5, 2008) (Extensions of Remarks of Rep. Sheila Jackson-Lee).

It is against this backdrop that GINA was enacted, despite employer objections to increased regulation over an area that seems to rarely surface in the workplace.

Genetic Information Defined

The act broadly defines genetic information as (1) an employee's genetic tests; (2) the genetic tests of the employee's family members; and (3) "the manifestation of a disease or disorder in family members of such individual." 42 U.S.C. §2000ff(4). It is this third portion of the definition of genetic information that is particularly problematic for employers. One problem is the definition of a "family member." Family members include dependents and first-, second-, third-, and fourth-degree relatives. This extraordinarily broad definition of family

members includes not only an employee's parents, siblings, children and grandchildren, but also an employee's first cousins, grand nephews and nieces, and great-great grandparents, among others. Further, the act covers genetic information about a fetus or an embryo resulting from assisted reproductive technology used either by a covered individual or a covered family member, although information about the sex or age of any individual is excluded from the definition of genetic information.

Genetic information also includes an individual's request for, or receipt of, genetic services, which is further defined as genetic testing, genetic counseling, which is interpreting or assessing genetic information, or genetic education. A genetic test is the analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations or chromosomal changes. The term genetic test does not include an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes, or an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that a health care professional with appropriate training and expertise could reasonably detect.

A second GINA problem area involves an employer's knowledge of disease or disorder manifestation in an employee's family member. Employer groups have opined that obtaining an employee's family history as a part of a personal medical history provides an employer with genetic information as defined by GINA. Bill Leonard, *The Stealth Statute: If You Think The New Genetic Information Law Doesn't Apply To You, Think Again*, HR MAGAZINE, December 2008, at 47. An employer might potentially obtain genetic information as defined under GINA during the application process for employer-sponsored health insurance benefits. *Id.* Another section of the act, however, may provide protection for employers with respect to information obtained during application for health insurance benefits. GINA provides that an employer will not be liable under the act for the use, acquisition or disclosure of "medical information that is not genetic information about a manifested disease, disorder, or pathological condition," even if the disease, disorder

or condition has a genetic basis. 42 U.S.C. §2000ff-9. Equal Employment Opportunity Commission regulations will likely provide more guidance outlining the specific parameters of "genetic information," and regulations must be issued no later than May 21, 2009.

Covered Parties

GINA borrows many definitions from Title VII of the Civil Rights Act of 1964, including the definition of an employer. The act has a much broader reach than Title VII, however, as it covers both private and public sector employers. In the private sector, the act covers employers with 15 or more employees. An employer is "a person engaged in an industry affecting commerce." 42 U.S.C. §2000e(b). Covered entities in the public sector include certain state employees, congressional employees, executive branch employees and other federal government employees, such as those employed by military departments, the United States Postal Service, and the Library of Congress, among others. In addition to employers, employment agencies and labor organizations are subject to GINA.

Individuals covered by the act include applicants for employment, as well as individuals employed by a covered employer.

Prohibited Acts

GINA prohibits unlawful employment practices against employees because of any genetic information "with respect to the employee." 42 U.S.C. §2000ff-1(a)(1). Similar to Title VII, unlawful employment practices involve discrimination with respect to hiring, firing and other terms and conditions of employment. It is also unlawful for an employer to use genetic information "to limit, segregate, or classify" an employee "in any way that would deprive or tend to deprive any employee of employment opportunities" or affect the status of employee. 42 U.S.C. §2000ff-1(a)(2). Further, the act prohibits employers from requesting genetic information, requiring an employee to provide genetic information, or purchasing genetic information about an employee. Exceptions to this prohibition are provided in the following instances:

- inadvertent requests or requirements for an employee's family medical history;

- health or genetic services provided in connection with wellness programs for which an employee has provided written authorization that restrict receipt of individually identifiable information to only the employee and the health care professional
- genetic information provided to the employer in aggregate or summary form,

Health insurance companies may not use genetic information to render individuals ineligible for coverage or determine premium rates.

- absent individually identifiable information so that the identity of specific individuals is not apparent;
- family medical history information requested in compliance with Family and Medical Leave Act certification procedures;
 - information that may contain family medical histories purchased from publicly available sources;
 - information used in connection with legally required genetic monitoring of the effects of toxic substances in the workplace, but only if the employer has provided written notice, the employee has given written authorization, the employee is informed of the results and the monitoring complies with state or federal genetic monitoring regulations; and
 - the employer is a forensics laboratory and requires genetic information as a quality control measure to ensure that samples have not become contaminated.

42 U.S.C. §2000ff-1(b).

Employment agencies and labor organizations are prohibited from causing an employer to discriminate against an employee due to genetic information relating to the employee or applicant or covered family member. Further, employers, employment agencies and labor organi-

zations may not discriminate against an individual with respect to apprenticeship training, or any other training or retraining.

Similar to other employee protection statutes, the act protects employees from retaliation for both opposing and complaining about unlawful employment practices. Employers may not retaliate against employees for alleging a GINA violation, for filing a charge or complaint, or for participating in an investigation or proceeding concerning an alleged GINA violation.

Confidentiality

Employers are required to keep genetic information confidential in maintaining such information. If an employer possesses genetic information concerning an employee or covered family member, the employer must maintain it “on separate forms and in separate files” as a separate, confidential medical record. Employers may comply with this GINA section by complying with the Americans with Disabilities Act’s provisions relating to confidential medical records, which will lessen the recordkeeping burden, since most employers should already keep separate, confidential employee medical files for employees.

Employers may only disclose genetic information in limited circumstances. An employer may disclose genetic information to an employee or family member after receiving a written request from the employee or family member. An employer may also disclose genetic information to occupational and health researchers; in response to a court order (however, if the court order was obtained without the employee’s knowledge, the employer must notify the employee); to government officials investigating compliance with GINA; to comply with Family and Medical Leave Act provisions; or to federal, state or local public health agencies concerning a contagious diseases that presents an imminent hazard.

Health Insurance

In addition to limiting the decisions that employers can make, GINA amends several federal laws to prohibit discrimination in health insurance coverage based on genetic information. In short, GINA pro-

hibits insurance companies and health maintenance organizations and any other group health plan or health insurance issuers from using genetic information to determine the premiums they charge or the amounts that groups covered by the plans must contribute for health insurance. This limitation does not apply to situations in which an individual enrolled in a plan has a disease or disorder that has manifested itself: in those circumstances, plans and issuers may increase premiums for the individual’s employer. Plans and issuers, however, may not use the manifestation of a disease or disorder in one individual as evidence supporting a premium increase for other similarly situated individuals who have not manifested the disease or disorder.

Similarly, when determining whether to insure an individual, health insurance companies may not use genetic information to render individuals ineligible for coverage or determine premium rates. Again, this prohibition comes with the caveat that insurance companies may use information about an individual’s disease or disorder manifestation to make coverage and premium decisions. Genetic information also may not be used to impose a pre-existing condition exclusion, although, again, manifestations of a disease or disorder may be used. Medicare supplemental policies must adhere to the same general rules: insurers may not deny coverage or establish policy eligibility in any way, or change the price of a policy based on an individual’s genetic information, but insurers may impose a limitation based on a manifestation of a disease or disorder in an individual, provided that such a limitation is not otherwise prohibited under federal law.

Both health plans and health insurance companies are prohibited under GINA from requesting or requiring an individual or his or her covered family members to undergo any genetic test. If an individual covered by an insurance plan is given a genetic test, plans and insurers may obtain and use the results of a genetic test to make a determination regarding payment, but they may only use the minimum amount of information necessary to make this determination.

Under GINA, health plans and insurance companies are prohibited from requesting,

requiring or purchasing genetic information of any kind for underwriting purposes prior to an individual's enrollment under a plan or policy. Plans and insurers may still collect health information related to the manifestation of a disease or disorder in an individual enrolled in, covered by, or who would potentially be covered by a plan or policy and use it for a permitted underwriting purpose with respect to that individual. Furthermore, genetic information that is collected incidental to the collection of other information is permissible under GINA as long as it is not used for underwriting purposes.

Research Permissible

GINA does not contemplate a bar to scientific research, so it includes an exception under which a group health plan or insurance company may request—but not require—a participant or beneficiary to undergo a genetic test if five conditions are met:

- the request is made in writing;
- the request is relevant for research that complies with federal law and any applicable state or local law;
- the request clearly indicates to each participant or beneficiary to whom the request is made that compliance is voluntary, and noncompliance will have no effect on enrollment status or premium contribution amounts;
- none of the genetic information collected is used for underwriting purposes, unless the plan or issuer notifies the appropriate federal agency in writing that it is conducting such research activities and provides a description of the activities conducted; and

- the plan issuer complies with such other conditions as required by applicable federal, state or local regulations.

Enforcement and Remedies

The enforcement and remedies provided by GINA are already familiar to most covered employers. Congress used the enforcement scheme provided under Title VII. Similar to claims filed under Title VII and the Americans with Disabilities Act, an employee may file a charge of discrimination with the Equal Employment Opportunity Commission (EEOC) within 180 days of an alleged unlawful, discriminatory practice under GINA, or within 300 days in states with a state law prohibiting discrimination in employment practice and that has an agency to investigate such claims that has a work-sharing agreement with the EEOC. As other charges filed with the EEOC, if the agency determines after an investigation that there is probable cause to believe a violation of the act has occurred, the EEOC may engage in conciliation. If conciliation fails, the EEOC may initiate a suit in the appropriate United States District Court. Alternatively, the EEOC may issue a letter called a Dismissal and Notice of Rights to the employee who has filed the charge. The employee has the option to initiate a suit in the appropriate United States District Court within 90 days of his or her receipt of the dismissal notice.

GINA provides for recovery of the same types of damages as in other cases of intentional employment discrimination. Complaining parties may recover both compensatory and punitive damages. Compensatory damages are capped at \$300,000 for employers with 500 or more employees, and

at lower levels for employers with fewer employees. There is no cap on punitive damages. Complaining parties are also entitled to recover attorneys' fees and costs.

The Path Forward

More guidance for compliance with GINA will be forthcoming as the EEOC issues its proposed regulations. The act requires the applicable regulatory agencies to issue regulations by May 21, 2009. While the EEOC's initial goal was to issue proposed regulations in January 2009, it was not able to adhere to that time frame. The states must incorporate GINA provisions into their health insurance regulatory schemes no later than July 1, 2009.

In the interim, counsel should advise employers to take several steps to ensure compliance with GINA. First, employers must determine whether they regularly conduct impermissible genetic tests in connection with pre-employment physicals or return to work examinations and stop impermissible tests. Second, employers should determine whether they possess employee genetic information, as it is broadly defined by the act, and ensure that such information is maintained as a confidential medical record separate from the individual's personnel file. Third, employers should review their wellness programs to ensure that genetic services, including testing and counseling, comply with GINA's requirements. Finally, GINA adopts language from Title VII requiring employers to post a notice advising employees of their rights. The form of the GINA notice must be prepared or approved by the EEOC and should be included in the EEOC's forthcoming regulations. 