

D R A F T

FOR DISCUSSION ONLY

**UNIFORM PROTECTION OF GENETIC
INFORMATION IN EMPLOYMENT
AND INSURANCE ACT**

NATIONAL CONFERENCE OF COMMISSIONERS

ON UNIFORM LAWS

For March 12-13, 2010 Drafting Committee Meeting

With Prefatory and Reporter's Notes

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February 21, 2010

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**UNIFORM PROTECTION OF GENETIC INFORMATION IN EMPLOYMENT
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UNIFORM PROTECTION OF GENETIC INFORMATION IN EMPLOYMENT AND INSURANCE ACT

Prefatory Note

The scientific developments in the field of genetics are often characterized as a “revolution.” This revolution is ushering in a new era of greater understanding of human biological processes and the promise of new approaches to medicine that can tailor medical treatments to individuals’ genetic traits. Genetic tests also offer the possibility of identifying individuals who are at risk of developing certain diseases in the future. Unfortunately, while risk information has the potential to improve preventative medicine, it is also subject to misunderstanding and misuse. This Act strikes a balance between making genetic information available for beneficial uses and preventing acquisition of information that creates a risk of misuse.

There are important policy issues concerning the appropriate form and scope of regulation of genetic information. Appropriate goals for regulation include that (1) individuals should not be coerced into having genetic tests; (2) individuals who want to be tested should not be discouraged through fear of how the results will be used; (3) genetic information should not be used for irrational discrimination, that is, where there is no scientific basis for discrimination; and (4) even “rational” discrimination should be prohibited when it violates public policy, including the policy of preventing discrimination on the basis of disability. Cynthia Nance, Paul Miller, & Mark Rothstein, *Discrimination in Employment on the Basis of Genetics*, 6 Employee Rights & Employment Policy Journal 57, 79 (2002). See also Henry T. Greely, *Genotype Discrimination: The Complex Case for Some Legislative Protection*, 149 U. Pa. L. Rev. 1483, 1500 (2001).

The Drafting Committee has articulated four concepts that support the goals of protecting privacy and encouraging testing: control, confidentiality, consent, and counseling. The principle of knowing and voluntary consent can allow an individual to control genetic testing by vesting the decision in the individual to be tested. A baseline rule of confidentiality, coupled with the individual’s capability to consent to exceptions, can allow an individual to control how others acquire, use, retain, or disclose the individual’s genetic information. Finally, given the complexities and uncertainties of genetic science, genetic counseling is necessary if these decisions about consent are to be knowing and informed.

The Drafting Committee has identified reasons why it is important to regulate genetic testing and acquisition, use, retention, and disclosure of genetic information by employers and insurers. These include the need to prevent fears of adverse consequences associated with genetic testing; the tendency to overstate the predictive power of genetic information, which can lead to actions that are not justified by that information; and the growing availability of genetic information.

Fear as a deterrent to genetic testing. To encourage individuals to undergo testing that can lead to advances in genetics and improved medical care, it is important to prevent fears that their privacy may be invaded or that testing may lead to detrimental treatment by employers or

insurers. Currently, the public is afraid of taking advantage of genetic testing. *See, e.g.,* Amy Harmon, *Fear of Insurance Trouble Leads Many to Shun or Hide DNA Tests*, N.Y. Times, Feb. 24, 2008, at A1. There is more than anecdotal evidence that these fears are widespread. In a 1997 national survey, 63% of the respondents reported that they would not take genetic tests if employers or insurers could obtain access to the results. Department of Labor, Department of Health & Human Services, Equal Employment Opportunity Commission, & Department of Justice, *Genetic Information and the Workplace* (Jan. 20, 1998) (available at <http://www.genome.gov/10001732>). In an actual genetic study of individuals at risk for hereditary colon cancer, only 43% of those eligible participated. Of those who declined, 39% said the primary reason was fear that the test results would affect their medical insurance coverage. D. Hadley, et al, *Genetic Counseling and testing in families with hereditary nonpolyposis colorectal cancer*, *Archives of Internal Medicine* 163: 573-582 (2003). These examples illustrate that individuals must have control not only over whether or not to undergo a test, but also over the information that results from genetic testing.

Exaggerated predictive power of genetic information. Because the human genome has been portrayed with images such as “blueprint,” “code,” and “future diary,” public misunderstandings of the role of genetics are common. Employers and insurers cannot be expected to be exempt from such misunderstandings, which may cause them to exaggerate the predictive potential of genetic information.

There are some rare genetic diseases, such as Huntington’s disease, that are caused by a single gene and that can be predicted with certainty from an individual’s genetic sequence. These diseases may arguably justify “rational” discrimination. But such monogenetic diseases are the exception. They have received much attention as the first diseases for which researchers established a genetic link, but they afflict relatively few individuals. And even with such diseases, there is usually variation in the age that symptoms appear and in their severity that lessens predictability.

The genetic causation of most diseases, and hence their predictability is far more complex. It is more common for medical conditions to result from interactions among multiple genes and with the environment. Most of the diseases that are linked to a genetic variation do not appear in all of the individuals with that genotype. This is termed “incomplete penetrance.” For example, certain forms of the BRCA 1 gene are strongly associated with susceptibility to breast cancer. But only 50 to 85 percent of women who have this form of the gene will ever develop the disease. Moreover, the frequency of particular gene variants and their degree of penetrance often differ among ethnic groups, which also complicates the clinical sensitivity of genetic tests and their predictive capabilities.

Another complicating factor for accurate prediction is that often a large number of genetic variations can cause the same disease. More than 180 different sequences of beta-globin genes are associated with the blood disease beta-thalassemia. And the severity of the symptoms of patients with this disease vary dramatically. Similarly, there are more than 300 forms of the gene responsible for cystic fibrosis. Unfortunately, identifying the variant of the gene does not explain the variation in symptoms.

Low penetrance, multiple genetic variations that may cause a single disease, and other sources of complications diminish the predictive value of genetic testing. In addition to the over-inclusiveness of many medical predictions based on genetic tests (in that a person with a predisposing genotype may never have symptoms of the disease), genetic predictions are also often extremely under-inclusive. For example, the predisposing variants of the BRCA 1 and BRCA 2 genes are present in only 5 to 10 percent of breast cancer patients. Thus, genetic data often do not provide an accurate individualized prediction. This is a major justification for the regulation of genetic information.

Increased Availability of Genetic Information. Scientific advances in genetics mean that a very large amount of information can be obtained from one small sample that is easily obtained and analyzed, yielding data that is easily stored and disseminated. This is not unique, but the concentration of information makes genetic information, which combines the power of many other types of medical information, seem particularly threatening.

Recent developments are making genetic information far more available and increasing the risk that it can be misused. One development is in genetic testing offered directly to consumers. Companies such as 23andMe and Navigenics offer a genome scan of a saliva sample for as little as \$1,000. There are companies that purport to help clients find DNA-compatible mates based on differences in immune systems or use DNA samples to identify nutritional needs that can be met by purchases of dietary supplements. *See generally* Rick Weiss, *Genetic Testing Gets Personal: Firms Sell Answers on Health, Even Love*, Wash. Post, Mar. 25, 2008.

A second development that will vastly increase the amount of readily available genetic information is the ongoing transition within the practice of medicine to electronic medical records. In 2005, the Secretary of Health and Human Services, Michael Leavitt, established the American Health Information Community, a federal advisory committee, to make recommendations on how to accelerate a shift to electronic records with the goal of reducing costs and improving medical care. Genetic information is typically contained in a standard medical record. Such records could be linked to each other and available electronically.

Scope of Regulation. Proposals to regulate genetic information, however, have provoked a major policy debate over the wisdom of “genetic exceptionalism,” that is, the regulation of genetic testing and information as a special category rather than as part of more comprehensive regulation of medical testing and information. *See generally* T.H. Murray, *Genetic Exceptionalism and Future Diaries: Is Genetic Information Different from other Information*, in *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (Mark A. Rothstein ed. 1977); Sonia M. Sutter, *The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?*, 79 Wash U. L.Q. 669 (2001).

In the course of this debate, many arguments for singling out genetics for special attention have been raised and rejected. In the early 1990s, the Task Force on Genetic Information and Insurance, a joint working group of the National Institutes of Health and the United States Department of Energy, considered and rejected three justifications for such a policy: (1) They decided that genetic information is not sufficiently distinct from other health information on the basis of its prophetic potential. Genetic predispositions can be affected by many factors and

information on non-genetic characteristics, such as lifestyle, may be better health predictors; (2) Genetic information is also not unique in its implications for family members; and (3) Genetic information is not the only type of health information with the ability to stigmatize.

Other arguments for exceptionalism include that genetic information is particularly sensitive in that it identifies normal variations that fuel discrimination despite their lack of clinical significance. Genetic codes are also viewed as immutable, so that one test can follow a person forever, and genetic information is more probabilistic than other types of medical information. These arguments can also be refuted as a basis for exceptionalism on the ground that they apply as well to other types of health information. Laine Friedman Ross, *Genetic Exceptionalism vs. Paradigm Shift: Lessons from HIV*, 29 J. L. Med. & Ethics 141 (2001).

There are also objections to treating genetic information separately on practical grounds. The distinction between genetic and non-genetic disorders is increasingly difficult to draw; most conditions have both a genetic and non-genetic component. Opponents of exceptionalism also contend that it is unrealistic to separate genetic information in medical records, so that it would be impossible to comply with restrictions on disclosing genetic information to employers or insurers. L.O. Gostin & J.G. Hodge, *Genetic Privacy and the Law: An End to Genetics Exceptionalism*, 40 Jurimetrics 21 (1999). Also, there is a social argument that it is unwise to enact laws that treat genetic conditions as if there is a stigma attached to them because that reinforces such attitudes and becomes a self-fulfilling prophecy. Moreover, treating genetics as unique only encourages the public view that genetics exert a special control over our lives, a view termed “genetic essentialism.” See, e.g., Rochelle Cooper Dreyfus & Dorothy Nelkin, *The Jurisprudence of Genetics*, 45 Vand. L. Rev. 313 (1992).

Most of the opponents of genetic exceptionalism do not oppose privacy protections, rather they advocate more holistic approaches to health information and its use in employment and insurance. The larger debate is about how to protect medical data from harmful uses while providing access for uses that individuals, clinicians, and society regard as beneficial. Genetic information is one part of the problem posed by the ease of collecting, storing, and disseminating personal information. Thus it is possible to argue that the exceptionalism debate is a distraction from more important questions about how regulations should be adapted to new scientific developments. Zita Lazzarini, *What Lessons Can We Learn from the Exceptionalism Debate (Finally)?*, 29 J. L. Med. & Policy 149 (2001). In the context of health insurance, one commentator maintains that “[g]enetic equity should be regarded not as an exceptional goal, but as an aim consistent with a broader movement toward equitable access to health care in a time of scarcity.” John V. Jacobi, *Genetic Discrimination in a Time of False Hopes*, 30 Fla. St. U. L. Rev. 363, 364 (2003).

The Drafting Committee’s charge, which covers the misuse of genetic information in employment and insurance, responds to the large number of states that have enacted legislation. That legislation is highly inconsistent and often deals only partially with the issues associated with genetic information. The charge does contemplate genetic exceptionalism by focusing on use of genetic information rather than on health information or privacy more generally. Broader measures for all medical information may not be practical at this time. Nonetheless, it is still important to respond to problems with the use of genetic information. Perhaps regulation of the

use of genetic information can serve as an example for policies that need to be developed for the treatment of medical information more generally.

Privacy Protections in General

General Policy Issues

The genetic revolution has raised challenges for several different aspects of privacy: informational privacy, physical privacy, decisional privacy, and proprietary privacy. See Anita L. Allen, *Genetic Privacy: Emerging Concepts and Values*, in *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* 31 (Mark A. Rothstein, ed. 1997).

Informational privacy can be thought of as an individual's ability to determine what information about that individual should be available to others. "By controlling personal information, individuals can control the extent to which other people can participate in their lives." David Orentlicher, *Genetic Privacy in the Patient-Physician Relationship*, in *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* 77 (Mark A. Rothstein, ed. 1997). Informational privacy of any type is challenging given advances in information technology that greatly increase the potential for others to acquire or disclose one's personal information.

In the genetic context, an individual's primary informational concern is the confidentiality or anonymity of the results of genetic testing. This privacy interest extends beyond the results of one's personal genetic testing to genetic testing of blood relatives, which can also provide information about the individual. The desire to maintain the privacy of this genetic information often has a consequential motivation: people are concerned about others using their genetic information to their detriment. It also springs from a sense of the intrinsic value of keeping such personal information private whether or not the release of genetic information could lead to adverse consequences. The understanding that one's characteristics, and even one's personality, are strongly linked to one's genetic composition heightens the sense that this information is a reflection of personal identity, and thus has inherent personal value.

The other forms of privacy are also important in the context of genetics. Physical privacy, the protection of bodily and personal space, is implicated by genetic testing or treatment. The importance of this form of privacy is recognized in concern for informed, voluntary consent for genetic testing. Decisional privacy, the freedom to make choices without interference by others, is implicated by the need to make decisions about using genetic services. Decisional privacy is an important tenet of genetic counseling, which supports autonomous decisionmaking about having genetic testing and learning the results of the testing. Proprietary privacy, control over possessions and economic interests, is implicated by the value of some individuals' samples or genetic information and by a sense of ownership of one's own identity. See Anita L. Allen, *Genetic Privacy: Emerging Concepts and Values*, in *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* 31 (Mark A. Rothstein, ed. 1997).

Privacy is valued in society and law, but not absolutely. The important interest in genetic privacy and confidentiality must be balanced against competing values, including facilitating

medical research, improving medical care, protecting public health, enforcing the law, and controlling costs.

The Federal Regulatory Context

State legislation on privacy of medical information is set against the background of the 1996 Health Insurance Portability and Accountability Act (HIPAA), which covers health insurers and other health practitioners, and the recently enacted Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. 110-233, which covers health insurers and employers.

Title II of HIPAA required the Department of Health and Human Services to promulgate rules that created standards for the use and dissemination of health care information, including what is now called “The Privacy Rule.” The Privacy Rule, which took effect in 2003, regulates those who create and disclose health information – individual practitioners, multi-national health plans, pharmacies, and information clearinghouses – but not many of the key recipients of this information. “Covered entities,” which include most health insurers, may disclose “protected health information,” i.e., “individually-identifiable health information” to facilitate treatment, payment, or health care operations. For other disclosures, with some exceptions, they must first obtain “consent,” “authorization,” or “agreement” from the individual, depending on the circumstances of the disclosure. The Privacy Rule also allows individuals access to their own health information and gives them the right to request a correction of any inaccurate data. Covered entities must notify individuals of uses of their protected health information and keep records of disclosures.

Health insurers who are covered entities must follow these rules when they disclose health information to employers or life, disability-income, or long-term-care insurers, but employers and these insurers are not directly subject to the HIPAA regulations and so do not need to follow these rules in their own treatment of the information.

Although HIPAA does include general preemption provisions, they do not apply to state laws that relate to the privacy of individually-identifiable health information that are contrary to and more stringent than the federal requirements. Thus HIPAA provides a floor, not a ceiling, for privacy protections and would not preempt the privacy provisions of the Act.

Recent federal legislation has established specific privacy requirements for genetic information. GINA supplements privacy regulations for group, individual and medigap health insurers already covered by the HIPAA privacy regulations. It prohibits these health insurers from requesting, requiring or purchasing genetic information before an individual’s enrollment and from using genetic information in underwriting or determining eligibility.

The legislation also limits acquisition, use, and disclosure of genetic information by employers, labor organizations, employment agencies, and joint labor-management committees. Its provisions do not apply to life, disability-income, and long-term-care insurers. Like HIPAA, the GINA employment provisions do not preempt state legislation that provides equal or greater privacy protection to individuals.

Current State Statutes

Approximately 15 states have statutes that protect the privacy of genetic information in general, without regard to employment or insurance or any other specific context. Most of these statutes are tailored to cover information derived from genetic testing, although some establish a principle of confidentiality for medical information more generally. (Cal, Maine, ND) Many of these statutes declare that genetic testing and test results are confidential. *See, e.g.*, Ariz. (confidential and privileged), Cal, Maine, New York, Oregon. A few states have established a property right in genetic test results. Alaska Stat. § 18.13.010 (exclusive property right in DNA sample and results of analysis performed on sample); Fla. Stat. § 760.40 (results of DNA analysis are the exclusive property of the person tested); OR (repealed)).

Most of these generally-applicable statutes prohibit obtaining, analyzing, retaining, or disclosing genetic test results without the informed consent or specific authorization of the tested individual. All these statutes also define exceptions where genetic information may be obtained or disclosures may be made without authorization. Typical exceptions include law enforcement purposes and paternity determinations. Some states also exempt certain forms of insurance. *See, e.g.*, Mass. (disability-income and long-term-care insurance); NH (life, disability-income, and long-term-care insurance); NMex (life, disability-income, and long-term-care insurance if underwriting based on sound actuarial principles); OK (life, disability-income, and long-term-care insurance). Others make special provisions for research. *See, e.g.*, NY; OR (repealed).

The NCCUSL Draft

This draft protects privacy through limitations on the ability of employers and insurers to require genetic tests and to acquire, use, retain, and disclose genetic information. These limitations are coupled with authorization requirements for voluntary testing and acquisition of their genetic information. In the section of the draft on employment, the privacy provisions are presented with information on GINA to enable the Committee to make policy decisions about the extent to which the Uniform Act should supplement the federal statute.

The Drafting Committee considered adopting a property right as a means to protect privacy of genetic information, but decided against this approach. While it might make sense to recognize a property right in genetic information in general, it is difficult to do only in the context of employment and insurance. Moreover, a majority of the Committee felt that a system of limitations on testing, acquisition, use, retention, and disclosure would be as effective as a property right in providing control over genetic information.

Employment

General Policy Issues

Many contend that employers' ability to obtain genetic information should be limited because it has few appropriate uses in the workplace. The concern is that if employers are permitted to consider genetic information in making personnel decisions, individuals may be unfairly barred or dismissed from employment for reasons that are not related to their ability to

do the job. This is an especially high risk with predictive genetic information because so many persons tend to exaggerate the role of genes in disease and mistakenly regard an increased risk of an illness as a certainty that it will occur.

Employers arguably have an economic incentive to use genetic information to avoid hiring employees with higher medical insurance claims, higher absenteeism, or lower productivity. They may also wish to avoid the effect of high health care costs incurred by employees' dependents. Somewhat perversely, because the federal Health Insurance Portability and Accountability Act (HIPAA) protects employees against discrimination in health insurance based on medical conditions, including genetic characteristics, the most effective way for employers to avoid high insurance costs is to screen applicants and avoid hiring high-risk individuals. Nonetheless, there are few well-documented cases of genetic discrimination in employment.

In 1996, the NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications of Human Genome Research (ELSI Working Group) and the National Action Plan of Breast Cancer developed and issued the following recommendations for state and federal policy makers to protect against genetic discrimination in employment. To a large extent, these recommendations mirror the approach of the Americans With Disabilities Act, described below.

- Employment organizations should be prohibited from using genetic information to affect the hiring of an individual or to affect the terms, conditions, privileges, benefits or termination of employment unless the employment organization can prove this information is job related and consistent with business activity.
- Employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information prior to a conditional offer of employment, and under all circumstances, employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information unless the employment organization can prove this information is job related and consistent with business necessity, or otherwise mandated by law. Written and informed consent should be required for each request, collection or disclosure.
- Employment organizations should be restricted from access to genetic information contained in medical records released by individuals as a condition of employment, in claims filed for reimbursement of health care costs and other sources.
- Employment organizations should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure will be made.

- Violators of these provisions should be subject to strong enforcement mechanisms, including private right of action.

Karen Rothenberg et al., *Genetic Information and the Workplace: Legislative Approaches and Policy Challenges*, 275 Science 1755 (1996).

The Federal Regulatory Context

The states are legislating in a regulatory environment in which recent federal legislation, the Genetic Information Nondiscrimination Act of 2008 (GINA), has increased the role of the federal government in regulating genetic testing and genetic information in employment. The employment provisions of this act do not, however, preempt state legislation that provides equal or greater protection to individuals. 42 U.S.C. § 2000ff-8(a)(1). In addition, two federal statutes provide modest legal protections against discrimination in employment on a genetic basis: Title VII of the Civil Rights Act of 1964 (Title VII) and the Americans with Disabilities Act (ADA). These statutes are also important because many states have their own version of these statutes which they have modified to incorporate genetic protections.

Recent federal legislation now specifically regulates acquisition of genetic information and its use by employers. 42 U.S.C. §§ 2000ff to 2000ff-11. GINA applies to employers, employment agencies, labor organizations, and training programs. These entities are prohibited from discriminating on the basis of genetic information. They are also prohibited from acquiring genetic information, with exceptions that include offering genetic services as part of an employer wellness program and genetic monitoring that is required by federal or state law. Employees may bring claims for disparate treatment based on genetic information, but not for disparate impact. In six years, a study group will make recommendations regarding whether or not to add a cause of action for disparate treatment. Remedies and enforcement are generally limited to those available under Title VII of the Civil Rights Act of 1964, which requires filing a claim with the Equal Employment Opportunity Commission.

GINA is supplemented by Title VII, which prohibits employer discrimination on the basis of race, sex, color, national origin, and religion. It is applicable to genetic discrimination if an employer tests a group of employees in one of the protected classes. For example, the court in *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9th Cir. 1998), held that testing only black employees for the sickle cell trait violated Title VII by imposing a condition of employment on the basis of race. It is also possible that testing all employees could violate the Act if the test were for a trait closely associated with a protected group, such as sickle cell trait (which is more prevalent among African-Americans) or Tay-Sachs disease (associated with Ashkenazi Jewish ancestry). However, in these circumstances the statute would require the difficult showing that the testing was a pretext for intentional discrimination against the group or that it had a statistically significant disparate impact on employment opportunities of members of the group. Most importantly, the narrow focus on employers' actions with respect to certain groups means that Title VII would certainly not apply if an employer instituted a screening program for traits that are not strongly associated with a protected group. See Pauline T. Kim, *Genetic Discrimination, Genetic Privacy: Rethinking Employee Protections for a Brave New Workplace*, 96 NW U. L. Rev. 1497 (2002).

The ADA could provide some protections against genetic discrimination through its regulation of disability discrimination, although this potential is limited by the United States Supreme Court's narrow interpretation of the statute. *See, e.g., Sutton v. United Air Lines, Inc.*, 527 U.S. 471, 484-85 (1999) (stating ADA is intended to have limited coverage). "Disability" is defined under the ADA as (1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual; (2) a record of such impairment; or (3) being regarded as having such an impairment. 42 U.S.C. § 12112(d)(2). If a genetically-caused disease results in a disability under the first prong of the definition, the ADA's protections will apply. The genetic connection is irrelevant; the statute protects the person because of the person's disability, not its cause. Similarly, under the second prong the ADA covers individuals with a prior history of a genetically-related disability, such as a person recovering from a cancer. Of course, if these genetic conditions do not qualify under the definition of "disability" by substantially limiting a major life activity, the individual is not covered by the ADA.

The application of the ADA to discrimination based on a genetic trait that is not manifested in symptomatic disease is a more difficult question. In 1995 the Equal Employment Opportunity Commission (EEOC) issued a policy statement that an individual should be "regarded as" having a disability under the statute's third prong if the employer discriminates on the basis of "genetic information relating to illness, disease, or other disorders." EEOC Order No. 915.002 § 902 (1995). This interpretation of the statute has not been considered by the courts, although several United States Supreme Court justices have expressed their disapproval in dicta. *See, e.g., Bragdon v. Abbott*, 524 U.S. 624, 661 (1998) (Rehnquist, J., joined by Scalia, J. & Thomas, J., concurring in part & dissenting in part). Moreover, the EEOC's position has been criticized in both conceptual and practical terms. *See, e.g., Pauline T. Kim, Genetic Discrimination, Genetic Privacy: Rethinking Employee Protections for a Brave New Workplace*, 96 NW U. L. Rev. 1497 (2002).

The ADA protects a disabled job applicant or employee from discrimination in the workplace. This includes a duty to provide reasonable accommodations to a qualified individual with a disability unless the accommodation would impose an undue hardship on the operation of the business. The ADA also regulates testing and acquisition of information by prohibiting medical examinations or testing before a job offer. However, after making a "conditional offer," an employer may require an applicant to take a medical exam. After making a conditional offer employers also have the right to require that individuals sign a blanket release disclosing all their medical records to the employer. Furthermore, once an individual is hired, an employer may test the employee if it can justify the testing as job-related.

Current State Statutes

Concern about economic incentives for employers has led 34 states, as of January 2006, to enact statutes that regulate the use of genetic information or genetic testing by employers. One group of states has used an existing state statute as a platform, amending it to apply to genetic testing or information. A second, larger, group has enacted statutes that are specifically tailored for genetic issues. This diversity of approaches has led to much inconsistency in state law.

In the first group, some states have extended their disability statutes to prohibit

discrimination by employers based on genetic information under the rubric of disability. *See, e.g.*, Hawaii RS §§ 378-1 to 378-6; Illinois, 410 ILCS 513/5 to 513/30 (tied to federal Americans with Disability Act); Mich Comp Laws Ann §§ 37.1201-37.1202; NY Exec Law §§ 292, 296 (adds genetic conditions to the definition of protected disability).

Other states in the group that has adapted existing statutes have built on their statutes that prohibit discrimination in employment, expanding them from race, sex, national origin, and other protected classes, to include discrimination based on genetic information. *See, e.g.*, Ariz Rev Stat Ann § 41-1463; Cal Govt Code §§ 12926, 12940; Conn Gen Stat Ann § 46a-60; Mass Gen L ch 151B; Nev Stat § 613.345; NJ Stat Ann §§ 10:5-5, 10:5-12. Wisconsin has used its Fair Employment Act as its vehicle, amending it to restrict the ability of employers to conduct genetic testing and use genetic information. Wis Stat § 111.372.

States in the second group have enacted special statutes that regulate genetic testing or the use of genetic information. This is the largest group of states, but the extent to which they concentrate on the context of employment varies to some extent. Most commonly, the provisions are tailored specifically for employment. *See, e.g.*, Ark Code Ann §§ 11-5-401 to 11-5-405; Del Code Ann § 710; Kan Stat Ann §§ 44-1002(m), 44-1009(a)(9); La Rev Stat Ann §§ 23.302, 23.368-369; Iowa Code § 729.6; Me Rev Stat Ann tit 5, § 19301; Md Code Ann art. 49B §§ 15,16; Minn Stat § 181.974; Neb Rev Stat § 48-236; NH Rev Stat Ann §§ 141-H:1 to 141-H:5; NC Gen Stat § 95-28.1A; Okla Stat tit 36, § 3614.2; Or Rev Stat § 659A.300; RI Gen Laws §§ 28-6.7-1 to 28-6.7-4; S.D. codified laws §§ 60-2-20 to 60-2-21; Tex Lab Code Ann § 21.401; Utah Code Ann §§ 26-45-101 to 26-45-106; Vt Stat Ann tit 18, §§ 9331-9335; Va Code Ann § 40.1-28.7:1(A); Wash Rev Code Ann § 49.44.180. Some statutes cover genetic information more broadly, regulating its use in employment along with insurance and other activities. *See, e.g.*, N Mex Stat Ann § 24-21-2. For other statutes, the focus is on broad regulation of genetic testing and information, with coverage that applies to employers along with others who might use the information. *See, e.g.*, Fla Stat § 760.4; NJ Stat Ann § 10:5-44, Or Rev Stat § 192.537.

The states that have special statutes limiting genetic testing or the use of genetic information in the employment setting have obviously embraced exceptionalism. But so, for the most part, have the states that have added discrimination based on genetic information to their employment discrimination statutes. This is the case because genetic characteristics are singled out and treated differently from other medical conditions under these statutes. An exception is California, whose statute prohibits employment discrimination on the basis of medical conditions in addition to the more traditional categories of race, sex, and national origin. Under this statutory scheme, a genetic characteristic is treated as a medical condition and receives the same protection as other health problems. Finally, disability statutes by definition single out certain types of medical conditions for special protection: those that are disabling because they limit a major life activity. When genetic predispositions or conditions are defined as disabilities, they are treated similarly to this class of medical conditions. However, to the extent that a genetic condition does not fit within the rubric of “limiting a major life activity,” it is being treated differently from other non-disabling medical conditions under these statutes.

The NCCUSL Draft

The draft presents a framework for the Drafting Committee to consider in structuring a state version of GINA, following the example of the state EEO statutes that supplement federal EEO law. It variously incorporates language from GINA, retains provisions from the prior NCCUSL draft, combines provisions, or offers alternative formulations. The goal is to present the Committee with a tool it can use to balance the goal of consistency with GINA with the policy decisions it has previously made to protect employees' genetic information.

Life Insurance, Disability-income Insurance, and Long-term-care Insurance

General Policy Issues

Life, disability-income, and long-term-care insurance can be distinguished from health insurance in that individual underwriting of policies is more common. This is because a larger proportion of the market for these insurance products consists of individual coverage than group coverage. According to the National Conference of State Legislatures, approximately 60 percent of life insurance, 40 percent of disability-income insurance, and almost all of long-term-care insurance is underwritten individually, compared to only about 10 percent of health insurance. Individual underwriting decisions take individual characteristics into account in determining risk and use this risk calculation in determining an individual's premium rates and the terms and conditions for coverage and benefits. Individual underwriting could be done more accurately with access to genetic information if that genetic information provides an accurate prediction of the likelihood of claims.

The argument for restricting acquisition of genetic information by the insurance industry is that its predictive power is easily exaggerated and insurers may force applicants to take genetic tests and then deny insurance or charge more based on genetic characteristics. This raises the possibility that a large class of people will lack coverage even though they are not sick and never will become sick. There are also privacy concerns with commercial acquisition of sensitive genetic information and predictions that individuals will avoid genetic testing for fear of adverse effects on their insurability. From the industry perspective, as with health insurance, insurers worry about adverse selection. If applicants seek coverage because a genetic characteristic exposes them to risk, but the insurer does not have this information, this puts the insurer at a financial disadvantage. *See generally* Mark A. Rothstein, ed., *Genetics and Life Insurance: Medical Underwriting and Social Policy* (2004).

The Federal Regulatory Context

Life, disability-income, and long-term-care insurance are not covered by the recent federal Genetic Information Nondiscrimination Act of 2008.

Obtaining, retaining, and disclosing information. The insurance industry is primarily regulated by the states, but there are federal laws that affect privacy procedures for some aspects of obtaining, retaining, or disclosing medical information. First, HIPAA is the primary source of privacy rules in the medical context. Long-term-care insurers, like health-care insurers, are

directly subject to the privacy rules in HIPAA.

Life and disability-income insurers are not directly subject to HIPAA, but their methods of obtaining medical information are affected indirectly because HIPAA controls the way in which health care providers can furnish them with medical information. Under HIPAA, the consumer must first provide an authorization for disclosure by the health care provider. Therefore, in order to obtain medical information from a health care provider to underwrite new coverage or evaluate a claim, an insurer's forms must meet HIPAA requirements for consumer authorization. HIPAA does not apply, however, to other forms of access, (such as genetic testing by a life or disability-income insurance company) or to the use, retention, or disclosure of genetic information by life or disability-income insurers.

Second, the Fair Credit Reporting Act affects insurers' ability to disclose as well as obtain medical information (including genetic information). It imposes requirements on obtaining, using, and disclosing "consumer reports." The term consumer report may include medical information, including genetic information, that is used as a factor in establishing eligibility for insurance. It does not, however, include medical information disclosed to an affiliate in connection with the business of insurance or annuities and hence such disclosures are not regulated by the act.

The Fair Credit Reporting Act was amended in 2003 by the Fair and Accurate Credit Transactions Act (FACT Act) in response to concerns about the use of medical information in determinations of eligibility for credit. Under the FACT Act, consumer reporting agencies may furnish a consumer report containing medical information in connection with an insurance transaction only with consumer consent. In addition, an insurer or other third party who receives medical information from an insurer in connection with the business of insurance may not re-disclose that information except as necessary to carry out the purpose for which the information was initially disclosed or as otherwise permitted by law.

Third, the Gramm-Leach-Bliley Act (GLBA) protects consumers from certain disclosures of their "nonpublic personal information." In general, this information may not be shared by a financial institution (including insurers) with an unaffiliated third party unless the consumer has been given notice and an opportunity to opt-out of such sharing. However, sharing without an opt-out opportunity is permitted if it is in connection with the performance of business activities or a joint marketing agreement between financial institutions. The GLBA requires state insurance regulators to adopt rules to implement and enforce its provisions. In doing so, many states have gone further in protecting medical information by requiring an authorization from the consumer (opt-in) before medical information may be shared, as described below.

The State Regulatory Context

Obtaining, retaining, and disclosing information. Disclosure of genetic information by insurers is covered under state provisions on general information practices in the insurance industry. First, about 18 states have adopted provisions based on the National Association of Insurance Commissioners' Insurance Information and Privacy Protection Model Act. These provisions require written authorization from a consumer before an insurer may share personal

consumer information, except as needed to perform basic insurance functions. *See, e.g.*, Ariz. Rev. Stat. §§ 20-2101 to 20-2102; Cal. Ins. Code §§ 791.01 to 791.23; Conn. Gen. Stat. §§ 38a-975 to 38a-999a; Ga. Code Ann. §§ 33-39-1 to 33-39-23; 215 Ill. Comp. Stat. Ann. 5/1001 to 5/1024; Me. Rev. Stat. Ann. tit. 24-A §§ 2201 to 2220; Mass. Gen. Laws ch 175I §§ 1 to 22; Minn. Stat. Ann. §§ 72A.49 to 72A.505; Mont. Code Ann. §§ 33-19-101 to 33-19-409; Nev. Admin Code §§ 679B.560 to 679B.750; N.J. Stat. Ann. §§ 17:23A-1 to 17:23A-22; N.C. Gen. Stat. §§ 58-39-1 to 58-39-125; Ohio Rev. Code Ann. §§ 3904.1 to 3904.22; Or. Rev. Stat. §§ 746.600 to 740.690; Va. Code Ann. §§ 38.2-600 to 38.2-620.

Second, in implementing the GLBA, 27 states have adopted provisions specifically protecting medical information from disclosure by insurance companies. These provisions are based on the National Association of Insurance Commissioners' Privacy of Consumer Financial and Health Information Model Regulation. It provides that an insurer may not disclose nonpublic personal health information unless the consumer has provided authorization or unless the disclosure is made in connection with insurance business functions. *See* Alaska Admin. Code tit. 3 §§ 26.605 to 26.749; Ark. Ins. Rule & Reg. 74; Cal. Fin. Code §§ 4050 to 4060; Colo. Admin. Ins. Reg 6-4-1; Conn. Admin. Code tit. 38a §§ 8-105 to 8-123; Fla. Admin. Code §§ 69O-128.001 to 69O-128.025; Iowa Admin. Code §§ 191-90.1 to 191-90.26; Kan. Admin. Regs. § 40-1-46; 806 Ky Admin. Regs. 3:210-3:220; Md. Admin. Code §§ 31.16.08.01 to 31.16.08.24; Neb. Rev. Stat. § 44-901 to 44-925; N.H. Admin. Code Ins. §§ 3001.01 to 3006.05; N.Y. Comp. Code R. & Regs. tit 11, §§ 420.0 to 420.24 (Reg. 169); N.D. Admin. Code §§ 45-14-01-01 to 45-14-01-25; Okla. Admin. Code §§ 365:35-1-1 to 365:35-1-54; Or. Admin. R. 836-080-0501 to 836-080-0551 & 836-080-0600 to 836-080-0700; 31 Pa.Code §§ 146a.1 to 146a.44 & 146b.1 to 146b.24; R.I. Code Regulation 100; S.C. Code Ann. Regs. 69-58; S.D. Admin R. 20:06:45:01 to 20:06:45:31; Tex. Admin Code §§ 22.1 to 22.67; Utah Admin Code 590-206; Vt. Code R. IH-2001-1; Wash. Admin Code §§ 284-04-120 to 284-04-260; W. Va. Code St. R. §§ 114-57-1 to 114-57-22; Wis. Admin. Code § § 25.01 to 25.95; Wyo Ins. Regs. ch. 54 §§ 1 to 26.

Use of Information. General limitations on the use of information in insurance underwriting are included in the Unfair Trade Practices Acts in effect in almost every state. These limitations apply to genetic information as well as to other information. Typically, these provisions prohibit "making or permitting any unfair discrimination between individuals of the same class and equal expectation of life in the rates charged for any life insurance policy or annuity . . . or in any other terms and conditions of such policy." National Association of Insurance Commissioners Model Unfair Trade Practices Act § 4(G)(1). In many states, disability-income and long-term-care insurance are regulated as health insurance. For health insurance, a typical provision prohibits "unfair discrimination between individuals of the same class and of essentially the same hazard in the amount of premium, policy fees or rates charged for any accident or health insurance policy or in the benefits payable thereunder, or in any of the terms and conditions of such policy, or in any other manner." § 4(G)(2).

In both life and health insurance, practices that constitute "unfair discrimination" between individuals of the same class are identified as "refusing to insure, refusing to continue to insure, or limiting the amount, extent, or kind of coverage available to an individual or charging a different rate for the same coverage solely because of a physical or mental impairment, except where the refusal, limitation or rate differential is based on sound actuarial principles or is related

to actual or reasonably anticipated experience.” National Association of Insurance Commissioners Model Regulation on Unfair Discrimination in Life and Health Insurance on the Basis of Physical or Mental Impairment § 3.

Some states also specifically regulate the use of genetic information in life, disability-income, or long-term-care insurance. Many of them reiterate their Unfair Trade Practices Act by requiring an actuarial justification for the use of genetic information in determining eligibility and in underwriting. This does not address, however, the important question of whether there is a sufficient scientific basis for assessing risk and how the sufficiency of that scientific basis should be determined. Moreover, an additional question in the genetic context is whether or not there are conditions that should be excluded from consideration even if there is an actuarial justification for different treatment.

A 1997 study by the Human Genetics Advisory Commission in the United Kingdom concluded that it is unlikely that actuarially-sound genetic predictions of adult death will be validated and available anytime in the near future. Genetic tests need to be connected to medical and epidemiological research to establish what consequences for health and life-span can be inferred from a given genetic test. The Commission concluded that a requirement to disclose genetic tests as a condition of obtaining insurance would be acceptable only after research has established an association between a given pattern of test results and life events that are relevant for the insurance product. They recommended continuing a moratorium on requiring test results. They also predicted that the life insurance industry could withstand the limited adverse selection that might result from non-disclosure. Human Genetics Advisory Commission, *The Implications of Genetic Testing for Insurance* (1997).

Current State Genetic Statutes

At least twenty-three states have legislation that regulates genetic testing or the use of genetic information in life, disability, or long-term-care insurance. Twenty-two states have statutes that pertain to life insurance, nineteen apply to disability insurance, and fifteen cover long-term-care insurance.

Obtaining and disclosing genetic information. The most common privacy protection in state law is a requirement for informed consent or authorization for genetic testing by the individual to be tested. Several states have general provisions requiring informed consent to obtain genetic information that are applicable to insurers. *See, e.g.*, Alaska Stat. §§ 18.13.010 (informed and written consent needed for DNA collection, analysis, retention, & disclosure); Del. Code Ann. § 1221(a) (same); Fla. Stat. Ann. § 760.40(2)(a) (informed consent necessary to perform DNA analysis). A larger number of states specifically require an individual’s informed consent or authorization for genetic testing for life, disability-income, or long-term-care insurance. *See* Ariz. Rev. Stat. Ann. § 20-448.02(A) (life, disability-income, long-term-care); Cal. Ins. Code § 10148 (life, disability-income); Colo. Rev. State § 10-3-1104.7(10)(a) (life, individual disability-income); Minn. Stat. Ann. § 72A.139 (life); Nev. Rev. Stat. Ann. § 629.151 (life); N.J. Stat. Ann. § 17B:30-12(f) (life, disability-income); N.Y. Ins. Law § 2615(a) (life, disability-income, long-term-care); Or. Rev. Stat. § 192.535 (life, disability-income, long-term-care); Vt. Stat. Ann. tit. 18, § 9332(d) (life, disability-income, long-term-care). In a couple of

states, insurers that require genetic tests must pay the cost of the test. Cal. Ins. Code § 10148 (life and disability-income); Minn. Stat. Ann. § 72A.139 (life).

Other states prohibit insurance companies from requiring genetic testing as a condition of obtaining insurance. For all three types of insurance, insurers may not require applicants in Massachusetts or Vermont to undergo a genetic test as a condition of issuing or renewing a policy. Mass. Gen. Laws Ann. Ch. 175, § 120E (life); Mass. Gen. Laws Ann. Ch. 175, § 108I (disability-income, long-term-care); Vt. Stat. Ann. tit. 18, § 9334(a). In California, there is a special provision for long-term-care insurance that prohibits insurers from requiring genetic testing to determine insurability or for underwriting. Cal. Ins. Code § 10233.1.

A couple of states impose restrictions on asking applicants for genetic information. In Kentucky, disability-income insurers may not request or require an applicant to disclose a genetic test. Ky. Rev. Stat. Ann. § 304.12-085(3). In contrast, in Massachusetts, all three types of insurers may ask if an applicant has taken a genetic test. The application form must indicate, however, that the applicant is not required to answer questions about genetic testing or genetic information, but that failure to answer may result in denial of coverage or an increased rate. Mass. Gen. Laws Ann. Ch. 175, § 120E (life insurance); Mass. Gen. Laws Ann. Ch. 175, § 108I (disability-income and long-term-care insurance).

Finally, some states also regulate disclosure of genetic information, requiring either informed consent or authorization of the individual tested. *See, e.g.*, Alaska Stat. §§ 18.13.010; Cal. Ins. Code § 10149.1. Another approach classifies genetic information with mental health information and HIV status as “sensitive health information” that requires protections against disclosure beyond that required for medical information. *See, e.g.*, Conn. Gen. Stat. § 38a-999. In terms of access to test results by the individual tested, some states require insurers to provide test results to the individual or the individual’s designated physician. *See, e.g.*, Fla. Stat. § 760.40(3) (general); Minn. Stat. Ann. § 72A.139 (life insurance); N.J. Stat. Ann. § 17B:30-12(f) (life & disability-income insurance, with option for genetic counseling); N.Y. Ins. Law § 2615(e) (if adverse decision for life, disability-income, or long-term-care insurance).

Use of genetic information. The broadest restrictions on use of genetic information prohibit insurers from using genetic testing results or genetic information to determine eligibility or for underwriting. *See* Colo. Rev. Stat. § 10-3-1104.7(3)(b) (group disability-income & long-term-care insurance); Kan. Stat. Ann. § 40-2259(d) (disability-income & long-term-care insurance). Arizona prevents disability-income and long-term-care insurers from using information about a genetic predisposition in underwriting by permitting those insurers to use genetic test results only if there is an actual diagnosis of a genetic condition. Ariz. Rev. Stat. Ann. § 20-448(F). Both Oregon and Vermont prevent all three types of insurers from using any genetic information about a blood relative for either eligibility or underwriting. Or. Rev. Stat. § 746.135; Vt. Stat. Ann. tit. 18, § 9334(a).

Other states restrict use of genetic information by prohibiting insurers from denying coverage or underwriting based on the applicant’s status as a carrier of a genetic disease. California specifies that life and disability-income insurers may not rely on information about an applicant’s genetic characteristic that causes no adverse effects on the carrier, even though it

might be associated with disability in the applicant's offspring. Cal. Ins. Code § 10143. These traits include, but are not limited to, Tay Sachs trait, sickle cell trait, thalassemia trait, and X-linked hemophilia A. Other states similarly prohibit insurance decisions based on specific genetic traits. *See* Fla. Stat. Ann. § 626.9706 (sickle-cell trait) (life); La. Rev. Stat. Ann. § 22:652.1(A), (D) (sickle-cell trait & severe disability) (life and disability-income); N.C. Gen. Stat. § 58-58-25 (sickle-cell trait & hemoglobin C trait) (life); Tenn. Code Ann. § 56-7-207 (sickle-cell trait & hemoglobin C trait) (life).

Finally, a number of state genetic statutes reiterate standards for underwriting that duplicate provisions of most state Unfair Practices Act, stating that the use of genetic information in underwriting must be based on an actuarial justification, may not be used for unfair discrimination, or must be reasonably related to risk. *See* Ariz. Rev. Stat. Ann. § 20-448(E) (life, disability-income, & long-term-care insurance); Kan. Stat. Ann. § 40-2259(d) (life insurance); 24A Me. Rev. Stat. Ann. § 2159-C(3) (life, disability-income, & long-term-care); Md. Code Ann., Ins. § 27-208(a)(3) (life, disability-income, & long-term-care insurance); Mass. Gen. Laws Ann. Ch. 175, § 120E (life, disability-income, & long-term-care insurance); Mont. Code Ann. § 33-18-206 (life, disability-income, & long-term-care insurance); N.J. Stat. Ann. § 17B:30-12(f) (life & disability-income insurance); N.M. Stat. Ann. § 24-21-4 (C) (life, disability-income, & long-term-care insurance); Vt. Stat. Ann. tit. 18, § 4724(3) (life, disability-income, & long-term-care insurance); Wis. Stat. Ann. § 631.89 (life & disability-income insurance).

The NCCUSL Draft

The draft allows life insurers, disability-income insurers, and long-term-care insurers to require genetic tests and use genetic information for coverage and underwriting decisions only as scientific developments justify that use. The draft places a burden on insurers to show that a positive genetic test is reliably associated with increased medical risk of mortality or morbidity. If an insurer can demonstrate that to a reasonable degree of scientific certainty, it can use the information. If the available scientific evidence does not meet this standard, use of the genetic information would be a violation of state unfair practices insurance law.

1 **UNIFORM PROTECTION OF GENETIC INFORMATION**
2 **IN EMPLOYMENT AND INSURANCE ACT**

3 **[ARTICLE] 1**

4 **GENERAL PROVISIONS**

5 **SECTION 101. SHORT TITLE.** This [act] may be cited as the Uniform Protection of
6 Genetic Information in Employment and Insurance Act.

7 **Reporter’s Notes**

8
9 In the early stages of drafting, the act was named “Misuse of Genetic Information in
10 Employment and Insurance Act.” In 2008, the ULC Executive Committee authorized changing
11 the name of the act to “Protection of Genetic Information in Employment and Insurance,” which
12 better reflects the scope of the act. The act deals not only with misuse, but also use, acquisition,
13 retention, and disclosure of genetic information, setting a balance that provides appropriate
14 protection for genetic information in all these contexts.

1 [ARTICLE] 2

2 EMPLOYMENT

3 SECTION 201. DEFINITIONS. In this [article]:

4 (1) “Credentialing authority” means a governmental or private entity that provides a
5 license, registration, or credential or certifies competence that is necessary for an individual to
6 qualify for employment or to participate in an occupation or profession.

7 (2) “Employee” means an individual who works for, or applies to work for,
8 compensation, an individual using or applying to use the services of an employment agency, a
9 member or applicant for membership in a labor organization, an apprentice, trainee or applicant
10 for a training or retraining program, or an individual or applicant considered by a credentialing
11 authority. The term includes an individual employed in, or applying for employment in, a
12 supervisory, managerial, or confidential position. The term does not include an independent
13 contractor.

14 (3) “Employer” means a person, including an agent of that person, that compensates
15 [five] or more individuals for each working day in each of twenty or more calendar weeks in the
16 current or preceding calendar year.

17 (4) “Employment agency” means a person, including an agent of that person, that
18 regularly undertakes, with or without compensation, to procure employees for an employer or to
19 procure for employees opportunities to work for an employer.

20 (5) “Employment entity” means an employer, employment agency, labor organization,
21 credentialing authority, or joint labor-management committee.

22 (6) “Family medical history” means information about the manifestation of a disease or
23 disorder in an individual’s family member.

1 (7) “Family member” includes a person who is a dependant of an individual as the result
2 of marriage, birth, adoption, or placement for adoption and a person who is a first-degree,
3 second-degree, third-degree, or fourth degree relative of the individual or of the individual’s
4 dependant. The term includes deceased members of the family.

5 (8) “Genetic condition” includes a genetic trait and a genetic disease or disorder.

6 (9) “Genetic counseling” includes:

7 (A) assessing an individual’s genetic risk for an inherited genetic condition by
8 interpreting family medical histories;

9 (B) providing nondirective education about the inheritance, testing, management,
10 and prevention of a genetic condition;

11 (C) helping an individual to understand the risks and benefits of testing for a
12 genetic trait to promote informed decision-making about whether or not to undergo genetic
13 testing;

14 (D) communicating and interpreting test results; and

15 (E) providing support, informational resources, and referrals as appropriate to help
16 an individual adapt to the medical, psychological, and familial implications of having or being at
17 risk of having a genetic condition.

18 (10) “Genetic education” means the process by which an individual acquires information
19 about the individual’s or the individual’s family member’s existing or suspected genetic
20 condition.

21 (11) “Genetic information” means information, other than information about the age or
22 sex of an individual, about the following:

23 (A) the individual’s genetic test;

1 (B) the genetic test of a family member of the individual;

2 (C) a manifested disease or disorder in family members of the individual;

3 (D) a request for, or receipt of, genetic services, or participation in clinical
4 research which includes genetic services, by the individual or a family member of the individual;
5 or

6 (E) the genetic test of a fetus carried by the individual or a family member of the
7 individual or an embryo legally held by the individual or a family member of the individual.

8 (12) “Genetic monitoring” means a periodic examination of an employee to evaluate
9 acquired modification to the employee’s genetic material, such as chromosomal damage or
10 evidence of increased occurrence of mutations, that may have developed in the course of
11 employment due to exposure to toxic substances in the workplace, in order to identify, evaluate,
12 and respond to the effects of or control adverse environmental exposures in the workplace.

13 (13) “Genetic service” means a genetic test, genetic counseling, or genetic education.

14 (14) “Genetic test” means an analysis of human deoxyribonucleic acid (DNA),
15 ribonucleic acid (RNA), chromosomes, proteins, or metabolites, that detects genotypes,
16 mutations, or chromosomal changes. The term does not include an analysis of proteins or
17 metabolites that does not detect genotypes, mutations, or chromosomal changes.

18 (15) “Individually-identifiable genetic information” means an individual’s genetic
19 information that includes an identification of the individual or information that could reasonably
20 be used to identify the individual.

21 (16) “Joint labor-management committee” means an entity, including an agent of that
22 entity, that establishes, offers, or controls apprenticeship or other training or retraining programs,
23 including on-the-job training programs.

1 (17) “Labor organization” means an organization, including an agent of the organization,
2 in which employees participate that exists for the purpose, in whole or in part, of dealing with
3 employers concerning grievances, labor disputes, wages, rates of pay, hours, or other terms or
4 conditions of employment.

5 (18) “Labor organization member” means a member or an applicant for membership in a
6 labor organization.

7 (19) “Manifested disease or disorder” means a disease or disorder that has been or could
8 reasonably be diagnosed by a health care professional with appropriate training and expertise in
9 the relevant field of medicine. It does not include a disease or disorder if the diagnosis is based
10 principally on genetic information or on the results of one or more genetic tests.

11 (20) “Person” means an individual, corporation, business trust, estate, trust, partnership,
12 limited liability company, association, joint venture, public corporation, government or
13 governmental subdivision, agency or instrumentality, or any other legal or commercial entity.

14 (21) “Record” means information that is inscribed on a tangible medium or that is stored
15 in an electronic or other medium and is retrievable in perceivable form.

16 (22) “Sign” means, with present intent to authenticate or adopt a record:

17 (A) to execute or adopt a tangible symbol; or

18 (B) to attach to or logically associate with the record an electronic symbol, sound,
19 or process.

20 (23) “Tribunal” means a court, arbitral tribunal, or administrative agency.

21 ***Legislative Note:*** In the definition of “employer” states may replace [5] with a lesser number of
22 employees in order to extend the coverage of the act.

Reporter's Notes

1
2
3 *Paragraph (1). (Credentialing authority)* Credentialing authorities are included in the
4 group of employment-related organizations labeled as “employment entities” and regulated in
5 this article. The draft act’s inclusion of credentialing authorities extends the coverage of GINA.
6

7 Credentialing authorities serve as gatekeepers to certain types of employment by
8 providing credentials that are required either under state law or by an employer. Examples
9 include state bar and medical examination boards, which control entry to the practice of law and
10 medicine, and state departments of motor vehicles, which issue commercial drivers licenses
11 necessary for some employment. Acquisition or use of genetic information by a credentialing
12 authority could have the same effects on employees and applicants for employment as acquisition
13 or use by an employer.
14

15 California’s state EEO statute similarly expands the protections of federal employment
16 law with regard to credentialing. It prohibits licensing boards from requiring an examination or
17 establishing any other qualification that has an adverse impact on a class by virtue of race, creed,
18 etc, unless the practice can be demonstrated to be job related. Cal. Gov. Code § 12944.
19

20 Pursuant to Section 210, the act does not affect occupational medical certifications, such
21 as a medical examination required for a school bus driver, when the entity that certifies the
22 medical qualification of the employee is a covered entity under HIPAA.
23

24 *Paragraph (2). (Employee)* The definition of employee is adapted from the National
25 Conference of Commissioners on Uniform State Law’s Model Employment Termination Act. It
26 differs from GINA’s definition, which defines an employee as an individual employed by an
27 employer.
28

29 For drafting ease, the term employee is used to also cover individuals who are labor
30 organization members, apprentices or trainees, or using employment agencies. Because GINA
31 combines its definitions of employee and applicant, the definition also includes applicants for
32 employment, labor organization membership, or an employment credential. The intent is to
33 cover any individual who is subject to collection of information or an employment decision by an
34 employment entity, which is defined as an employer, employment agency, labor organization,
35 credentialing authority, or joint labor management committee.
36

37 The definition’s requirement for compensation is intended to exclude volunteers from the
38 definition of employee. In addition, the Drafting Committee decided to exclude independent
39 contractors from the definition of employee. This approach is not intended, however, to provide
40 employers with an avenue to evade their obligations by classifying employees as independent
41 contractors.
42

43 *Paragraph (3). (Employer)* GINA defines employment by reference to the Civil Rights
44 Act of 1964. The draft follows the format of the underlying definition, using language adapted
45 from Title VII (42 U.S.C. § 2000e (b)). However, Title VII and the proposed federal regulations
46 implementing GINA define an employer as someone who employs an employee. The act avoids

1 this circularity by defining the employment relationship in terms of compensation. It avoids the
2 term employee because it is defined in this act to include applicants for employment, labor
3 organization members, apprentices or trainees, and individuals using employment agencies.
4

5 *Size of employers.* Like Title VII of the Civil Rights Act of 1964, GINA covers
6 employers with 15 or more employees. Many state employment discrimination statutes expand
7 the scope of their coverage beyond that provided by Title VII by including employers with
8 smaller workforces. The draft follows this approach by setting the threshold for coverage at 5 or
9 more employees. Many states may want to reduce the number of employees required to trigger
10 the act's coverage and the legislative note gives them the option to do this.
11

12 In deciding whether to include smaller employers under the act's coverage, states should
13 consider the thresholds they have enacted in other statutes, such as their state employment
14 discrimination statute and their workers compensation statute. For example, 16 jurisdictions
15 cover all employers (i.e., employers with one or more employees) under their state employment
16 discrimination acts. An additional 10 states have set a threshold below that of the draft, ranging
17 from two to four employees.
18

19 *Types of employers.* The draft's definition of employer is linked to the definition of
20 "person." It therefore encompasses all types of entities, including governmental and non-profit
21 employers. This is consistent with the coverage specified by a number of states in their state
22 versions of Title VII of the Civil Rights Act of 1964 on employment discrimination. (See, e.g.,
23 Hawaii, Iowa.)
24

25 *Paragraph (4). (Employment agency)* This is the definition provided in GINA.
26

27 *Paragraph (5). (Employment entity)* Employment entity is the term used in the act to
28 collectively indicate an employer, an employment agency, a labor organization, a credentialing
29 authority, or a joint labor-management committee that offers training programs. The definition
30 expands GINA's coverage by adding credentialing authorities.
31

32 The regulations implementing GINA use the term "covered entity" to group the
33 organizations covered by the federal act. This term is not used in the draft because of the
34 potential for confusion with the use of the term "covered entity" in HIPAA and because the act's
35 scope of coverage is slightly different from GINA, which does not include credentialing
36 authorities.
37

38 *Paragraph (6). (Family medical history)* Family medical history is often a source of
39 genetic information in that it is used to evaluate the likelihood that an individual carries an
40 inherited trait. The act's employment article follows GINA and includes family medical history
41 within its definition of "genetic information." The term "family medical history is not defined in
42 GINA. This definition follows the definition in the proposed regulations implementing GINA. It
43 is somewhat different from the definition in the prior draft, which was "information about a
44 current or past medical condition of a family member of an individual."
45

46 *Paragraph (7). (Family member)* The draft defines family member to encompass all

1 individuals whose genotype could influence an employment decision. The term includes (1)
2 dependants of an employee whose risk of future genetically-linked medical conditions could
3 affect employer health care costs or the cost of family insurance coverage and hence affect
4 employment decisions, (2) biological relations of an employee whose genetic information might
5 provide information about the genetic make-up of the employee, and (3) biological relations of
6 an employee’s dependants, whose genetic information might provide information about the
7 genetic make-up of a dependant.
8

9 *Definition’s relationship to GINA.* The draft adopts the definition of family member used
10 in the EEOC’s proposed GINA employment regulations. GINA itself defines “family member”
11 by using the term “dependent” with reference to ERISA’s use of that term in its provisions on
12 special enrollment periods for group health plans, 29 U.S.C. § 1181(f)(2). As used in ERISA,
13 this status depends on the scope of health care coverage offered by the employer. A person can
14 be a “dependent” only if a group health plan makes coverage available for them and the person
15 they are dependent on is enrolled in the plan. The EEOC’s definition omits the reference to
16 health care plans in order to “further Congress’s intent to prohibit genetic discrimination in the
17 employment context, and provide[] [employers] with clear standards governing compliance with
18 the law.”
19

20 The prior draft defined family member to mean “an individual’s spouse or [domestic
21 partner], child, and all individuals related by whole or half blood within the fourth degree of
22 consanguinity measured using the civil law method to the individual, the individual’s spouse or
23 [domestic partner], or the individual’s child.” This differed from the current definition by
24 including domestic partners on the rationale that many employers provide health insurance for
25 employees’ unmarried partners and therefore, an unmarried partner can be a dependent whose
26 risk of a genetically-linked medical condition could affect employment or insurance decisions.
27 The brackets around this term were meant to indicate that a state should substitute the term it
28 uses for a person in this relationship. The Drafting Committee decided to omit the provision
29 covering domestic partners in order to further consistency between the act and GINA.
30

31 *Degree of relationship to the individual or the individual’s dependents.* The definition
32 follows GINA and the proposed EEOC regulations by including relatives of an employee or the
33 employee’s dependants to the fourth degree of consanguinity. Genetic counselors typically
34 collect information on genetic diseases of family members related to the third degree of
35 consanguinity and often to the fourth degree.
36

37 The proposed EEOC implementing regulations list these family members. The Drafting
38 Committee considered listing family members within the fourth degree of consanguinity in the
39 act’s definition, but decided to include this information in the notes instead.
40

41 Lineal consanguinity is the relationship between persons when one is directly descended
42 from the other. Each generation in this direct line constitutes a degree. Collateral consanguinity
43 refers to the relationship between persons who descend from the same common ancestor, but not
44 from each other. The civil law method of calculating degree of collateral consanguinity counts
45 the number of generations from one person up to the common ancestor and then down to the
46 other person. The proposed GINA regulations state that they determine the degree of relationship

1 by counting the generational levels separating the individuals. Although the civil law method of
2 calculation is reportedly often used by the states to determine the degree of consanguinity, the
3 chart below is based on the specifications in the proposed EEOC regulations. Each row
4 represents a generation and the degree of consanguinity is given in parentheses.

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				Great-great-grandparents (4)
			Great-grandparents (3)	
		Grandparents (2)	Great Aunts and Great Uncles (3)	
	Parents (1)	Aunts and Uncles (2)		
Individual	Sisters and Brothers and half-siblings (1)	First Cousins (3)		
Children (1)	Nieces and Nephews (2)	First Cousins once-removed (4)		
Grandchildren (2)	Grandnieces and Grandnephews (4)			
Great-grandchildren (3)				
Great-great-grandchildren (4)				

1 *Paragraph (8). (Genetic condition)* This is a new definition in this draft. This term is
2 used in the definitions of genetic counseling and genetic services. It is not used or defined in
3 GINA. The definition is intended to give the term a broad interpretation. A genetic condition
4 includes a manifested genetic disease or disorder as well as a genetic trait that may increase the
5 likelihood of developing a disease or disorder. However, the term may also refer to a positive or
6 benign trait or characteristic that is linked to a particular genotype.

7
8 *Paragraph (9). (Genetic counseling)* Genetic counseling is a key to an individual’s
9 informed decision making about getting a genetic test, understanding the result, and authorizing
10 its use, retention, or disclosure. GINA defines genetic counseling by inserting the following
11 parenthetical about genetic counseling into its definition of a genetic service: “(including
12 obtaining, interpreting, or assessing genetic information).” The Drafting Committee concluded
13 that a more comprehensive definition is important because genetic counseling is a relatively new
14 profession and state regulation of genetic counselors and genetic counseling is currently in flux.
15 Some states license or certify genetic counselors and they tend to have a definition of genetic
16 counseling. But the majority of states do not license genetic counselors or regulate genetic
17 counseling and hence lack a definition.

18
19 It is important to note that the definition does not require that genetic counseling be
20 performed by a genetic counselor. Physicians, geneticists, and nurse practitioners are also
21 qualified to provide genetic counseling.

22
23 Genetic counseling is usually a two-step process consisting of 1) counseling before a test
24 about the decision whether or not to have the test and 2) counseling after the test if the test
25 indicates the individual is at risk. In addition, for some conditions counseling may also be
26 appropriate if the test indicates the individual is not at risk. The functions listed in (A)-(C) of the
27 definition of genetic counseling take place before an individual decides whether or not to have
28 the test. The functions in (D) and (E) take place after the test, if necessary.

29
30 *Paragraph (10). (Genetic education)* Genetic education is one element of genetic
31 services. It is typically less tailored to individual circumstances than a one-on-one genetic
32 counseling session. The definition is meant to be broad enough to include information provided
33 by support groups for genetic conditions to those who may have the condition. It is not meant to
34 encompass general genetic education such as that received in biology class or medical school.
35 This term is used, but not defined, in GINA.

36
37 *Paragraph (11). (Genetic information)* This definition of “genetic information” follows
38 the definition in the employment title of GINA. It includes a family member’s genetic tests. It
39 also includes family medical history more generally through a reference to the occurrence of a
40 disease or disorder in family members of the individual.

41
42 The definition incorporates GINA’s provisions on the genetic information of fetuses,
43 which are found, not in GINA’s definitions, but in § 209, codified at 42 U.S.C. § 2000ff-8.
44 Under GINA, if an employee or family member is a pregnant woman, references to her genetic
45 information include that of the fetus she is carrying. If an employee or family member is using
46 assisted reproductive technology, references to that individual’s genetic information include the

1 genetic information of any embryo held legally by that individual.

2
3 This definition of genetic information is consistent with many states that define “genetic
4 information” to include information on genetic characteristics broadly, whether obtained from
5 genetic tests or family medical history. (Cal, Conn, Hawaii, LA, Maine, MD, Mass, Mich, NJ,
6 NMex, NC, RI, SD, TX, WA).

7
8 This definition now differs from the definition of genetic information used in Article 3 on
9 life, disability-income, and long-term-care insurance. That article allows these insurers to
10 continue to their traditional practice of collecting information on family history, even though
11 family history is a major source of information to evaluate an individual’s genetic risks.

12
13 *Paragraph (12). (Genetic monitoring)* The definition of “genetic monitoring” follows
14 the definition in GINA. It is drawn from the description in Office of Technology Assessment,
15 *Genetic Monitoring and Screening in the Workplace* 4 (1990). The focus in monitoring is not on
16 inherited characteristics, but on genetic alterations in a group of exposed individuals over time.
17 Genetic monitoring is typically undertaken by employers to identify risks for groups of
18 employees who have been exposed to hazardous substances or to target work sites for safety and
19 health measures. Testing for this purpose is permitted in Section 202.

20
21 *Paragraph (13). (Genetic service)* This definition follows the definition of “genetic
22 services” in the employment title of GINA. “Genetic service” is a broader category than genetic
23 testing. The term includes activities associated with obtaining genetic information that could
24 create assumptions about an individual’s genetic status even in the absence of information about
25 genetic test results or medical history. “Counseling” implies a one-on-one consultation, so the
26 definition also includes “genetic education” in order to capture group information sessions on
27 genetic conditions. While the definition of a “genetic service” does not separately define the
28 term “genetic,” the term should be interpreted to be consistent with the definitions of “genetic
29 test” and “genetic information.”

30
31 *Paragraph (14). (Genetic test)* This is identical to the definition of genetic test used in
32 GINA employment provisions. “Genetic test” is defined in terms of (1) the material that the test
33 analyzes and (2) what the test detects.

34
35 The first clause makes specific reference to the types of biological material that are
36 currently analyzed in genetic tests. Note that genetic tests can be conducted not only on gene
37 sequences, but also on biological products such as proteins or metabolites that can indicate
38 genetic make-up. The second clause specifies that the test must function to determine an
39 individual’s genetic make-up, either through the identification of a genotype or by looking for a
40 mutation or chromosomal change.

41
42 Both clauses are equally important to the definition. First, some of the materials listed in
43 the first clause, especially proteins and metabolites, are tested for many medical purposes. A test
44 of a protein or metabolite does not constitute a genetic test unless it is administered to determine
45 an individual’s genetic make-up as specified in the second clause.

1 Insurance industry representatives have expressed the fear that this definition is so broad
2 that it will sweep in routine medical tests such as blood tests of lipoproteins to measure
3 cholesterol levels. It is true that a cholesterol test analyzes proteins. A cholesterol test is not,
4 however, given specifically to detect a genotype, genetic marker, mutation, or chromosomal
5 change, so it would not be considered a genetic test under the draft. Instead, a high cholesterol
6 reading may indicate a number of causal factors, including inappropriate diet, lack of exercise,
7 and/or a condition called inherited familial high cholesterol. If the measurement of cholesterol
8 leads a doctor or insurance company to do further testing to see if an individual has a specific
9 genotype, then that would be a genetic test under the draft's definition. Other common medical
10 tests of proteins or metabolites that would not fall under the definition of "genetic test" include
11 urine tests for kidney disease, blood protein and creatinin tests for diabetes, blood tests of liver
12 enzyme proteins for liver function, urine tests measuring glucose to diagnose diabetes, blood
13 tests measuring serum blood glucose for diabetes, and triglycerides for heart disease. The second
14 sentence of the definition, although redundant, should reassure those who fear the definition will
15 be used to sweep in medical tests that are not given to detect genotypes, mutations, or
16 chromosomal changes.

17
18 The draft's definition is consistent with state definitions of genetic testing that are not
19 limited to identifying genotypes associated with diseases or impairments. (Fla, Haw, Mass, NH,
20 Ore, UT). In contrast, many other states statutes limit their definition of "genetic test" to testing
21 for disease-related genes. (Ariz, Ark, Del, Ill, Iowa, Kan, LA, Maine, MD, Mich, Minn, Nev,
22 MO, Neb, NJ, NM, NY, NC, OK, OR, RI, TX, VT, VA, WI). These definitions are not as
23 protective as the definition in GINA, and thus these statutes are likely preempted. While most of
24 the reasons that an employer or insurer might currently seek or use genetic information probably
25 involve a disease, disorder, or impairment, this may not always be the case. One can imagine, for
26 example, that the presence or absence of behavioral traits might also be a criterion for selecting
27 an employee. While the current evidence linking behavior to genes is tenuous, this area
28 continues to be the subject of investigation.

29
30 *Paragraph (15). (Individually-identifiable genetic information)* This definition is
31 included because the concept is used in the provisions allowing employment entities to acquire
32 genetic information for the purpose of offering health and genetic services and conducting
33 genetic monitoring programs. The concept is also used, but not defined, in the proposed GINA
34 regulations and is drawn from the HIPAA Privacy Rule, which protects individually-identifiable
35 health information. Under the Privacy Rule's definition, individually-identifiable health
36 information is health information that "identifies the individual[,] or [w]ith respect to which there
37 is a reasonable basis to believe the information can be used to identify the individual." 45 C.F.R.
38 § 160.103.

39
40 The HIPPA Privacy Rule does not directly indicate what information triggers a
41 reasonable basis to believe that it could be used to identify an individual, but it does provide a
42 standard for "de-identification" of protected health information. Health information is not
43 individually-identifiable if the following has been removed: names; all geographic subdivisions
44 smaller than a State, including street address, city, county, precinct, zip code, and their equivalent
45 geocodes (except for the initial three digits of a zip code if, according to the current publicly
46 available data from the Bureau of the Census, the geographic unit formed by combining all zip

1 codes with the same three initial digits contains more than 20,000 people); all elements of dates
2 (except year) for dates directly related to an individual, including birth date, admission date,
3 discharge date, date of death; all ages over 89 and all elements of dates (including year)
4 indicative of such age (except that such ages and elements may be aggregated into a single
5 category of age 90 or older); telephone numbers; fax numbers; electronic mail addresses; social
6 security numbers; medical record numbers; health plan beneficiary numbers; account numbers;
7 certificate/license numbers; vehicle identifiers and serial numbers, including license plate
8 numbers; device identifiers and serial numbers; web Universal Resource Locators (URLs);
9 internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints;
10 full face photographic images and any comparable images; and any other unique identifying
11 number, characteristic, or code. 45 C.F.R. § 164.514 (b).

12
13 *Paragraph (16). (Joint labor-management committee)* This definition is taken from the
14 proposed regulations implementing GINA.

15
16 *Paragraph (17). (Labor organization)* This definition is the one used in the proposed
17 regulations implementing GINA, omitting GINA’s requirement that the organization be engaged
18 in interstate commerce. It is similar to the following definition, which is commonly used in state
19 EEO acts: “‘Labor organization’ means any organization which exists and is constituted for the
20 purpose, in whole or in part, of collective bargaining or of dealing with employers concerning
21 grievances, terms or conditions of employment, or of other mutual aid or protection in
22 connection with employment.” (e.g., Cal., Colo., Hawai’i, Iowa, Minn, NY)

23
24 *Paragraph (18). (Labor organization member).* This definition is taken from GINA for
25 the purpose of including applicants within the scope of the definition.

26
27 *Paragraph (19). (Manifested disease or disorder).* This definition is taken from the
28 proposed EEOC regulations to implement GINA. It is relevant to the definition of genetic
29 information in this section and to Section 212, which excludes from the act’s coverage medical
30 information about a manifested disease or disorder that is not genetic information.

31
32 *Paragraph (20). (Person)* This draft uses the broad version of the standard National
33 Conference of Commissioners on Uniform State Laws definition of “person.”

34
35 *Paragraph (21). (Record)* The definition of “record” is the standard National Conference
36 of Commissioners on Uniform State Laws definition.

37
38 *Paragraph (22). (Sign)* The definition of “sign” is the standard National Conference of
39 Commissioners on Uniform State Laws definition.

40
41 *Paragraph (23). (Tribunal)* The term “tribunal” refers collectively to the potential
42 decision-makers in a litigation or arbitration context.

1 **SECTION 202. ACQUISITION OF GENETIC INFORMATION.**

2 (a) Except as otherwise provided in this article, an employment entity may not:

3 (1) request, require, purchase, or otherwise intentionally acquire genetic
4 information of an employee or an employee’s family member; or

5 (2) unless allowed by law other than this [act], require, offer, or provide a genetic
6 test to an employee or an employee’s family member.

7 (b) It is not a violation of this article if an employment entity inadvertently requests or
8 requires genetic information of an employee or an employee’s family member.

9 (c) An employment entity may acquire an employee’s genetic information if the employee
10 voluntarily submits the genetic information to the employment entity and authorizes the
11 employment entity’s acquisition in accordance with Section 203.

12 (d) An employment entity may request or require family medical history from an
13 employee to comply with the certification provisions of the Family Medical Leave Act, 29
14 U.S.C. § 2613, or of the [state family and medical leave act].

15 (e) An employment entity may obtain documents, other than by purchasing medical
16 databases, that are publicly available, including newspapers, magazines, periodicals, and books,
17 even if they contain an employee’s or an employee’s family member’s genetic information.

18 (f) An employment entity may acquire an employee’s or employee’s family member’s
19 genetic information and may offer and provide genetic testing to an employee or employee’s
20 family member in accordance with subsection (h) for use in providing health or genetic services
21 to an employee or employee’s family member, including as part of a voluntary wellness program,
22 if:

23 (1) an employment entity that offers a genetic test provides genetic counseling

1 about the risks and benefits of a genetic test before the employee or employee's family member
2 considers authorizing the test unless the employee or employee's family member knowingly and
3 voluntarily waives counseling before the test in a signed record that contains information about
4 the benefits of genetic counseling;

5 (2) the employee or employee's family member authorizes the employment entity
6 to acquire genetic information or the genetic testing in accordance with Section 203;

7 (3) the employee's or employee's family member's genetic information is used
8 only in providing health and genetic services to the employee or employee's family member;

9 (4) individually-identifiable genetic information is provided only to the employee
10 or, if the employee's family member is receiving genetic services, to the employee's family
11 member, a health-care professional designated by the employee or employee's family member,
12 and a licensed health care professional or board-certified genetic counselor involved in providing
13 the employment entity's genetic services; and

14 (5) genetic information is not disclosed to the employment entity except in an
15 aggregate form under circumstances that do not disclose the identity of the individual employee
16 or employee's family member.

17 (g) An employment entity may acquire an employee's genetic information and may offer
18 and provide genetic testing to an employee to conduct genetic monitoring of the biological
19 effects of toxic substances in the workplace if:

20 (1) the employment entity provides written notice of the genetic monitoring to the
21 employee;

22 (2) the genetic monitoring is:

23 (A) required by state or federal law; or

1 (B) authorized by the employee in accordance with Section 203 after the
2 employment entity provides and pays for genetic counseling for the employee about the risks and
3 benefits of the genetic test, unless the employee knowingly and voluntarily waives counseling in
4 a signed record that contains information about the benefits of genetic counseling;

5 (3) the genetic monitoring is in compliance with:

6 (A) federal genetic monitoring regulations, including regulations that may
7 be promulgated by the Secretary of Labor pursuant to the Occupational Safety and Health Act of
8 1970, 29 U.S.C. 651 et seq., the Federal Mine Safety and Health Act of 1977, 30 U.S.C. 801 et
9 seq., or the Atomic Energy Act of 1954, 42 U.S.C. 2011 et seq.; or

10 (B) this state's genetic monitoring regulations if this state implements
11 genetic monitoring regulations under the authority of the Occupational Safety and Health Act of
12 1970; 29 U.S.C. 651 et seq.;

13 (4) the employment entity pays for the genetic testing and the genetic counseling
14 required by subsection (h);

15 (5) individually-identifiable genetic information is provided only to the employee,
16 a health-care professional designated by the employee or employee's family member, and a
17 licensed health care professional or board-certified genetic counselor involved in providing the
18 employment entity's monitoring program; and

19 (6) genetic information is not disclosed to the employment entity except in an
20 aggregate form under circumstances that do not disclose the identity of the individual employee.

21 (h) An employment entity that provides a genetic test to an employee or employee's
22 family member as part of health or genetic services offered under subsection (g) or for a genetic
23 monitoring program under subsection (g) must:

1 (1) require the testing organization to report the test result to the tested individual
2 and a health-care professional designated by the individual unless the individual directs
3 otherwise;

4 (2) provide genetic counseling for the tested individual about a positive test result;

5 (3) require the destruction of the tested individual's biological sample obtained for
6 a genetic test as soon as permitted by law after the test is completed unless retention of the
7 sample is authorized by the individual in a knowing and voluntary authorization indicated in a
8 record signed by the individual, permitted by law other than this [act], or ordered by a tribunal.

9 (i) An employer that conducts DNA analysis for law enforcement purposes as a forensic
10 laboratory or for purposes of identifying human remains may request or require genetic
11 information or genetic testing of an employee to the extent necessary to analyze DNA
12 identification markers for quality control to detect sample contamination.

13 (j) When an employee has placed the employee's health at issue in a proceeding before a
14 tribunal in which an employment entity is a party, the employment entity may obtain genetic
15 information about the employee without the employee's authorization only if:

16 (1) the genetic information is relevant to a claim or defense in the proceeding;

17 (2) on a motion by the employment entity, a tribunal orders the employee to take a
18 genetic test or provide genetic information after finding that the employment entity has
19 demonstrated a compelling need and that the information is otherwise unavailable; and

20 (3) the employment entity pays for the genetic test if one is ordered by the
21 tribunal.

22 **Legislative Note:** In subsection (e), states should insert for [state family and medical leave act]
23 the appropriate name for the state's act.
24

1 **Reporter’s Notes**

2
3 *Applicability of Article 2.* This article is intended to apply broadly in the employment
4 setting to any employment entity. Employment agencies, labor organizations, credentialing
5 authorities, and joint labor-management committees offering training programs are included
6 within the scope of the article in addition to employers because they control access to
7 employment through referrals or licensing.
8

9 As explained in the Reporter’s Notes under section 201, the article expands the scope of
10 GINA and makes it more protective of employees. It does this by 1) covering all employers, not
11 only those with more than 15 employees and 2) by regulating credentialing authorities along with
12 the other employment entities.
13

14 *General approach to acquisition of genetic information.* Section 202 imposes a general
15 prohibition on genetic testing of employees or employee’s family members and on acquisition of
16 their genetic information. It then establishes a number of limited exceptions for situations in
17 which genetic testing by employment entities and/or their access to employee’s genetic
18 information is acceptable. The exceptions provided in GINA are supplemented with additional
19 provisions designed to provide greater protection for employees.
20

21 *Rationale for prohibiting acquisition and testing.* One rationale for limiting employer
22 acquisition of genetic information is the view that an employee should be able to keep genetic
23 information private. At least one state has a constitutional right of privacy that appears to be
24 relevant to genetic information. (Alaska) Another rationale is to make genetic discrimination
25 less likely. Unlike discrimination based on sex or race, an employer cannot discriminate on the
26 basis of genetic characteristics unless it has access to genetic information.
27

28 *Existing state law and its relationship to GINA and this act.* There are many avenues by
29 which employment entities obtain health information, which may include genetic information.
30 These include employment applications, interviews, references, post-offer medical exams, post-
31 offer releases of medical records, Family and Medical Leave Act requests, workers’
32 compensation claims, health insurance claims to self-insured employers, and voluntary
33 disclosures by employees. Many states have tried to limit employer acquisition of genetic
34 information. They have used a variety of approaches. Some statutes are consistent with GINA;
35 others are less protective and thus preempted.
36

37 First, many states have statutes that prohibit an employer from obtaining genetic
38 information. *See, e.g.,* La. Rev. Stat. § 23:368 (employer may not “require, collect, or purchase”
39 protected genetic information with respect to an employee); Mich. Comp. Laws § 37.1202 (no
40 employer may “directly or indirectly acquire or have access to” an employee’s or family
41 member’s genetic information unless an individual provides it voluntarily). These statutes do not
42 provide as extensive protection as GINA, which additionally prohibits employers from asking for
43 genetic information. The rationale for this protection is that in the context of at-will employment
44 the need to retain one’s job may turn an employer’s request for genetic information into a
45 demand that an employee dare not refuse. There are some state statutes that, like GINA, do
46 prohibit such requests. *See, e.g.,* Conn. Stat. Ann. § 46a-60(11) (employer may not “request or

1 require” genetic information from employee); Nev. Rev. Stat. § 613.345 (unlawful employment
2 practice to “ask or encourage” an employee to submit to a genetic test).
3

4 Many state statutes prohibit employers from obtaining information, and may also prohibit
5 requests, but arguably they are not as protective as GINA because they prohibit acquisition of
6 genetic information only for certain uses. *See, e.g.*, Kan. Stat. Ann. § 44-1009(a)(9) (employer
7 may not seek to obtain, obtain, or use testing information to distinguish employees or restrict a
8 right or benefit); Md. Code Art. 49B § 16(a) (employer may not “request or require” genetic
9 information as a condition for hiring or determining benefits); Mass. Gen. L. Art. 151B § 4(19)
10 (unlawful to “collect, solicit or require disclosure of genetic information” as a condition of
11 employment or “question a person about their genetic information or genetic information
12 concerning their family members”); Minn. Stat. Ann. § 181.974(subd. 2) (employer may not
13 “request, require, or collect” protected genetic information as a condition of employment); Neb.
14 Rev. Stat. § 48-236 (employer may not require genetic information as a condition of employment
15 or promotion); Utah Code Ann. § 26-45-103 (employer may not “access or otherwise take into
16 consideration” private genetic information in connection with an employment decision); Wash.
17 Rev. Code Ann. § 49.44.180 (unlawful to require employee to submit genetic information as
18 condition of employment). While GINA (and this Uniform Act) prohibit certain uses of genetic
19 information, they also place a value on employee privacy and, subject to limited exceptions, they
20 prohibit the acquisition of genetic information without regard to its use.
21

22 Second, many states broadly prohibit employers from subjecting employees to genetic
23 testing. *See, e.g.*, Kan. Stat. Ann. § 44-1009(a)(9) (employer may not subject, directly or
24 indirectly, any employee to any genetic screening or test); RI Stat. § 28-6.7-1 (employer may not
25 “request, require, or administer” a genetic test). Again, however, many states prohibit genetic
26 testing only for certain uses or when it is a condition of employment, which arguably is not as
27 protective as GINA. *See, e.g.*, Iowa Code Ann. § 729.6 (employer may not “solicit, require, or
28 administer” a genetic test as a condition of employment); Md. Code Art. 49B § 16(a) (employer
29 may not “request or require” genetic tests as a condition for hiring or determining benefits);
30 Mass. Gen. L. Art. 151B § 4(19) (unlawful to “solicit submission to, require, or administer a
31 genetic test” as a condition of employment); Mich. Comp. Laws § 37.1202 (no employer may
32 require a genetic test as a condition of employment); Minn. Stat. Ann. § 181.974(subd. 2)
33 (employer may not “administer a genetic test” as a condition of employment); Neb. Rev. Stat. §
34 48-236 (employer may not require a genetic test as a condition or employment or promotion);
35 Nev. Rev. Stat. § 613.345 (unlawful employment practice to “require or administer” a genetic
36 test as a condition of employment); N.H. Rev. Stat. § 141-H (may not “solicit, require, or
37 administer” genetic testing as a condition of employment); Utah Code Ann. § 26-45-103
38 (employer may not “request or require” an individual or blood relative to submit to a genetic test
39 in connection with an employment decision); Vt. Stat. Ann. § 9333 (may not require genetic
40 testing as a condition of employment); Va. Code Ann. § 40.1-28.7-1 (employer may not “request,
41 require, solicit, or administer” a genetic test as a condition of employment); Wash. Rev. Code
42 Ann. § 49.44.180 (unlawful to require employee to submit to genetic screening as condition of
43 employment); Wis. Stat. Ann. § 111.372 (employer may not “solicit, require, or administer” a
44 genetic test as a condition of employment unless employee requests test). GINA does not contain
45 prohibitions on testing, which is regarded as a form of acquiring genetic information and thus
46 covered by the provisions limiting employer acquisition. The Uniform Act, in contrast, is more

1 explicit. It contains a general prohibition on genetic testing and, in the narrow circumstances
2 singled out as exceptions, provides employees with protections that relate specifically to testing.
3

4 Other states do not provide the protections required by GINA because they rely on state
5 anti-discrimination statutes, which typically allow employers to compel testing or to require
6 employees to provide genetic information under certain circumstances. Many of these states rely
7 on disability statutes to regulate genetic information, usually following the Americans with
8 Disabilities Act (ADA), which permits an employer to test an applicant and acquire an
9 applicant's medical records after a conditional offer of employment. 29 C.F.R. § 1630.14(b).
10 This approach opens the door broadly to genetic information once an employer has made a
11 conditional offer of employment. In addition, under the ADA and most state statutes modeled on
12 it, after an employee is hired, an employer can obtain medical information if it has a reasonable
13 belief that the employee is unable to perform the essential functions of his or her job due to a
14 medical condition. 29 C.F.R. § 1630.14(c). Other states have amended their employment
15 discrimination statutes to include genetics. Under the rubric of these statutes, genetic testing or
16 collection of genetic information is typically permitted when it is relevant to "job-related
17 qualifications" or justified by "business necessity." The Drafting Committee considered and
18 rejected these approaches because of a concern that tying the Act's protections to the concept of
19 "job-related" medical information would not provide adequate protection for genetic information.
20 In interpreting the ADA, some courts have interpreted the category of "job-related" medical
21 information broadly, thus permitting employers to access medical information and narrowing the
22 scope of protection.
23

24 The draft's approach also contrasts with California's and Minnesota's more
25 comprehensive limitations on employer access, which prohibit employers from accessing non-
26 job-related medical information at any time. An advantage of California's and Minnesota's
27 approach is that it does not depend on how "genetic information" is defined. In addition, it does
28 not rely on custodians of medical files to make a distinction between genetic information and
29 medical information more generally, which are usually mixed in medical files. Practically
30 speaking, when an employee signs a release permitting employer access to medical records,
31 everything in the records is included. There are those who maintain that legislation is needed to
32 limit an employer's ability to obtain any non-job-related health information during the hiring
33 process or employment. See Mark A. Rothstein, *Genetic Exceptionalism and Legislative*
34 *Pragmatism*, 35 Hastings Center Report No. 4 (2005), at 35. The Drafting Committee discussed
35 this approach, but declined to adopt it because it extends beyond the scope granted to the
36 Committee.
37

38 *Subsection (a) General prohibition on acquisition of genetic information and genetic*
39 *testing.* This subsection establishes a general prohibition on acquisition of genetic information
40 by employment entities by prohibiting employment entities from "requesting, requiring, or
41 purchasing" an employee's genetic information. It also supplements GINA, which does not have
42 provisions that specifically cover genetic testing, by establishing a general rule that an
43 employment entity may not offer or provide genetic tests to employees. Subsections (b)-(j)
44 establish limited exceptions to the prohibition on acquisition. Subsections (f)-(j) establish
45 limited exceptions to the prohibition on genetic testing and set requirements for counseling and
46 reporting that must be met if an employment entity provides a genetic test.

1 The prohibition on acquisition uses the language of GINA by making it a violation for an
2 employer to “request, require, or purchase” genetic information. To avoid the possibility of a
3 restrictive interpretation of that language and to emphasize in conjunction with subsection (b)
4 that it is *intentional* acts by the employment entity that are prohibited, the subsection additionally
5 prohibits any other intentional acquisition of genetic information. The prohibition of requests is
6 intended to apply to inquires directed to other entities as well as to inquiries directed to the
7 employee or the employee’s family member.
8

9 Because the definition of genetic information includes information about access to
10 genetic services, the limitations in the act, like those of GINA, allow employees to keep private
11 information that could lead to discrimination based on assumptions about genetics, even in the
12 absence of actual genetic test results. If an individual is unable to keep private his use of genetic
13 services such as counseling, the individual may be deterred from obtaining this service for fear
14 that an employer will assume the employee has reason to think he has a genetic disorder.
15 Protection of this information is consistent with provisions in a number of states that prohibit
16 employers from acquiring or using information about an employee’s request for or use of genetic
17 services. *See, e.g.*, La. Rev. Stat. § 23:368 (employer may not “require, collect, or purchase”
18 information about an employee’s request for or use of genetic services); Maine Rev. Stat. Ann. §
19 19302 (employer may not discriminate on basis that an individual received a genetic test or
20 genetic counseling except when based on a bona fide occupational qualification); N.C. Gen. Stat.
21 Ann. § 95-28.1A (unlawful to deny employment of account of request for genetic testing or
22 counseling services); Utah Code Ann. § 26-45-103 (employer may not inquire into whether an
23 individual or blood relative has taken or refused to take a genetic test); Vt. Stat. Ann. § 9333
24 (employer may not use the fact that genetic counseling or tested services have been requested or
25 performed).
26

27 The prohibition on requesting genetic information is not intended to prevent an employer
28 from informing an employee about the availability of a genetic test that is relevant to conditions
29 in the workplace or from informing an employee about a genetic monitoring program.
30

31 *Exceptions to the general prohibitions on acquisition and testing.* Subsections (b)-(j),
32 described individually below, provide situations in which employment entities’ access to genetic
33 information and/or genetic testing is acceptable. The draft permits employment entities to
34 acquire genetic information if they request it inadvertently, receive it from an employee who
35 provides it voluntarily, request it under the Family Medical Leave Act, obtain it in certain
36 publicly available documents, obtain it as part of offering a voluntary wellness program, use it for
37 genetic monitoring, use it for quality control in forensic testing laboratories, or pursuant to a
38 tribunal’s order in litigation. An employment entity may provide genetic testing as part of a
39 wellness program and provide it or, when appropriate, require it for a genetic monitoring
40 program, for quality control use in forensic testing laboratories, or pursuant to a tribunal’s order
41 in litigation.
42

43 The Drafting Committee was informed that an employment entity that provides genetic
44 testing under one of these exceptions should supply it through an outside medical organization.
45 *See* Mark A. Rothstein, *Genetics and the Workforce of the Next Hundred Years*, 2000 Colum.
46 Bus. L. Rev. 371 (2000). The act, however, recognizes that this may not be the case and includes

1 these provisions to protect privacy in wellness and monitoring programs.

2
3 *Subsection (b) Inadvertent requests.* This subsection is included in the act for consistency
4 with GINA. Congress enacted this provision to address the “water cooler problem” – when an
5 employer unwittingly receives information through casual conversation or by overhearing
6 conversations. While GINA’s exception is expressly limited to requests for family medical
7 history, the proposed regulations expand it to include any genetic information on the theory that
8 it should not matter whether the employee is discussing a genetic test or a relative’s disease. For
9 consistency, the Uniform Act follows this approach.

10
11 The proposed EEOC regulations include examples of circumstances in which the
12 acquisition of genetic information would be deemed inadvertent. These include overhearing
13 conversations, receiving information that is not solicited, genetic information submitted in
14 response to a request for medical information, and information submitted by an employee
15 seeking an accommodation or leave.

16
17 Employment entities are urged, however, to take proactive measures and establish best
18 practices to avoid even inadvertent acquisition of genetic information. For example, if an
19 employer asks an employee to support a request for an accommodation by having a health care
20 professional provide documentation about a disability, the request form should instruct the health
21 care professional not to provide family medical history or other genetic information.

22
23 *Subsection (c) Information voluntarily provided by employee.* This section is not found in
24 GINA. It is derived from the prior ULC draft to supplement GINA’s exception for information
25 an employer obtains inadvertently by authorizing an employee to purposely provide an employer
26 with genetic information at the employee’s initiative. This recognizes employee autonomy and
27 would be protective of an employee if, for example, the employee sought reassignment to avoid
28 exposure to a chemical which the employee might have a genetic susceptibility. In addition,
29 when coupled with the authorization in section 203, it allows the employee to control the privacy
30 of the information the employee provides to the employer. This provision would also protect an
31 employer from liability under the act if an employee submits genetic information in a situation in
32 which the employment entity’s acquisition is not inadvertent.

33
34 Employees who provide genetic information voluntarily may do so directly, through oral
35 statements or by turning over reports of test results. They may also do so indirectly by permitting
36 an employment entity to see medical records held by a third party. The prior draft required prior
37 authorization by the employee only when the voluntary disclosure was made by a third party to
38 an employer. The authorization requirement was changed in this draft to parallel GINA’s
39 authorization requirements when an employee provides genetic information to an employment
40 entity as part of a wellness program or for a genetic monitoring program that is based on
41 employee consent. When medical records are provided to an employment entity by a third party,
42 it is likely that the third party will be a covered entity under HIPAA and the employee will need
43 to authorize the disclosure.

44
45 *Subsection (d) Family Medical Leave Act.* This subsection was added for consistency
46 with GINA. The exception is limited to requests for family medical history. The exception is

1 necessary because an employee seeking leave to care for an ill relative is asked about the
2 relative's illness on FMLA certification forms.

3
4 *Subsection (e) Publicly-available documents.* This subsection was added for consistency
5 with GINA. GINA has an exception when employers "purchase" commercially available
6 materials that may contain family medical history. The proposed EEOC regulations expand the
7 scope of this provision to include any genetic information for the reasons discussed in the notes
8 on subsection (b).

9
10 GINA explicitly includes newspapers, magazines, periodicals, and books as "excused"
11 media and excludes medical databases and court records. The proposed EEOC regulations
12 expand the list of excused media to include the internet, television, and movies.

13
14 The exception in this subsection differs from GINA and its implementing regulations in
15 that it is not limited to the purchase of media on the excused list. The Drafting Committee
16 decided that employment entities also should be permitted to obtain this material without cost.
17 The Committee regards the acquisitions covered in this subsection as examples of situations in
18 which an employment entity does not intend to acquire genetic information.

19
20 This subsection also differs from GINA in that GINA excludes purchasing court records
21 from the exception, thus effectively prohibiting employment entities from obtaining certain court
22 records. This draft excludes the purchase of medical databases, but not the purchase of court
23 records. The inclusion of genetic information in court records does pose a threat to employee's
24 privacy in that data miners are obtaining information from court records to sell to employers,
25 landlords, and others. However, court records are public records and the Drafting Committee
26 concluded that under the First Amendment and the principle of open courts, a state may not
27 statutorily prohibit access to court records by the public, including employment entities. In order
28 to protect employee privacy, courts should therefore adopt strong policies to redact genetic
29 information from court records.

30
31 *Subsection (f) Employee health or genetic services.* This subsection permits an employer
32 that provides preventative health services to encourage a healthy workplace to include genetic
33 testing and other genetic services as part of its program. These provisions are intended to
34 encourage employers to provide their employees access to genetic services in this way. The
35 employment entity must, however, meet the requirements listed in the statute as a prerequisite to
36 the acquisition of genetic information for this purpose.

37
38 GINA provides that an employment entity may offer health or genetic services as part of a
39 wellness program. This draft follows the proposed EEOC regulations in limiting the application
40 of this subsection to wellness programs that are voluntary. This is a requirement set forth in the
41 ADA. Under EEOC guidance, a wellness program is voluntary "as long as an employer neither
42 requires participation nor penalizes employees who do not participate." EEOC's Enforcement
43 Guidance on Disability-related Inquiries and Medical Examinations of Employees under the
44 Americans with Disabilities Act, 8 Fair Empl. Prac. Man. (BNA) 405, Question 22 (July 27,
45 2000), available at <http://www.eeoc.gov/policy/docs/guidance-inquiries.html>.

1 As under GINA, the ULC draft requires employee authorization before genetic
2 information can be used in providing health or genetic services. Requirements for employee
3 authorization for genetic testing and for acquisition of genetic information are set forth in Section
4 203.

5
6 The current draft includes GINA’s provision permitting access for a health care
7 professional involved in providing the services for the employment entity. The Drafting
8 Committee has been advised that employer-provided genetic counseling should normally be
9 conducted by professionals – typically genetic counselors, geneticists, or physicians – from
10 outside the employer organization. This act is not intended, however, to regulate the practice of
11 medicine, and so it does not directly forbid an employer from using employees to provide these
12 services. If an employer does use employees, it would be necessary for the health care
13 professional providing genetic services to obtain the genetic information of participating
14 employees. The intent of the current draft is to segregate that information so that it is used only
15 in providing genetic services and others in the employment entity do not have access to the
16 information in an individually-identifiable form. Hence, any genetic information otherwise
17 acquired by the employment entity must be in an aggregate form that does not disclose the
18 identity of the individual. However, employment entities that obtain aggregate information may
19 still violate the act if a small number of participants or other factors make an individual’s genetic
20 information readily identifiable from the aggregate information.

21
22 The draft also provides additional protections not found in GINA. In this subsection it
23 requires employers to provide genetic counseling about the risks and benefits of the test before an
24 employee considers signing the authorization for testing. The purpose of this counseling is so
25 that the employee can make an informed decision about whether or not to have the test. The
26 Drafting Committee decided that an employee may, however, decline the counseling. In
27 addition, in subsection (h), the draft mandates additional protections whenever an employment
28 entity provides genetic testing. These protections apply to both health or genetic services offered
29 by an employment entity and to genetic monitoring programs.

30
31 Prior ULC drafts provided that the employer must pay for the genetic testing and genetic
32 counseling. This differs from GINA. Because this testing is for the employee’s benefit and
33 might be covered by health insurance, the payment provision is dropped from the current draft.

34
35 In addition to this subsection and GINA’s employment provisions and implementing
36 regulations, Title I of GINA places restrictions on the genetic information that group health plans
37 may request or require from covered individuals. Employment entities that sponsor or maintain
38 group health plans that implement wellness programs should consult the regulations issued by the
39 Department of Labor, Health and Human Services, and the Department of the Treasury
40 concerning limitations on acquisition of genetic information by group health plans.

41
42 As provided in Section 210, the act is not intended to apply to uses of information
43 covered by the privacy regulations (Privacy Rule) that implement the 1996 Health Insurance
44 Portability and Accountability Act (HIPAA), which covers health insurers and other health
45 practitioners. Nothing in this subsection should be read to apply to or restrict the acquisition use,
46 or disclosure of genetic information that is subject to the HIPAA Privacy Rule. For example, if a

1 university employee becomes a patient in the university’s hospital, in that setting the individual’s
2 genetic information would be covered by the HIPAA Privacy Rule, not the provisions of this act.
3

4 *Subsection (g) Genetic monitoring program.* Monitoring for damage to employees’ genes
5 from workplace exposure to harmful substances is another possible justification for testing.
6 Genetic monitoring programs are typically undertaken by employers to identify risks for groups
7 of employees who have been exposed to hazardous substances or to target work sites for safety
8 and health measures. Monitoring is testing designed to detect whether the genetic material of a
9 group of individuals has changed over time. The premise is that such changes could indicate
10 increased risk of future illness. Aggregated data from tests for genetic damage is sufficient to
11 allow an employer to reduce exposures to levels that do not affect individuals’ chromosome
12 morphology or DNA. Office of Technology Assessment, *Genetic Monitoring and Screening in*
13 *the Workplace* 66 (1990). However, while monitoring may have predictive value for a group, the
14 techniques that are used do not currently measure increased individual health risks.
15

16 This draft and GINA both permit genetic testing in conjunction with a genetic monitoring
17 program with the authorization of the employee or, without employee authorization, when
18 required by federal or state law. It expands GINA’s protections by including a provision for
19 genetic counseling when the testing is conducted pursuant to an employee’s authorization. Both
20 GINA and this draft limit employer access to aggregate genetic data, with an exception for
21 employees administering the monitoring.
22

23 In addition, when an employer provides genetic testing as part of a genetic monitoring
24 program, this draft provides protections for the employee in subsection (h) that go beyond GINA.
25

26 *Reference to federal genetic monitoring regulations.* GINA, and this draft, require that an
27 employer’s genetic monitoring program must comply with federal regulations governing genetic
28 monitoring programs. The intent is to include future federal regulations and amendments.
29 Currently, the language refers to regulations that “may be promulgated.” One alternative
30 suggestion is to refer to regulations that “have been or are hereafter promulgated.” The Drafting
31 Committee seeks guidance from the Style Committee on appropriate wording to signal that the
32 requirement includes compliance with both existing and future federal regulations, as amended.
33

34 *Existing State law and its relationship to GINA.* A number of states permit genetic
35 monitoring, provided that the employee requests testing, provides informed consent or
36 authorization, and the employer does not terminate the employee or take other adverse action as a
37 result of testing. Iowa Code Ann. § 729.6(7); N.H. Rev. Stat. § 141-H:3; N.Y. Exec. Law § 296;
38 Wis. Stat. Ann. § 111.372. In addition, Louisiana authorizes monitoring of biological effects of
39 toxic substances in the workplace if the employee has provided authorization and is notified of
40 the results. La. Rev. Stat. § 23:368. More generally, the definitions and prohibitions in many
41 states’ statutes do not appear to restrict monitoring for genetic damage, or are ambiguous on this
42 issue. Thus many state statutes do not appear to provide safeguards for employees consistent
43 with GINA.
44

45 *Subsection (h) Protections in conjunction with genetic testing.* This subsection provides
46 the employee with protections in the event that an employment entity provides testing as part of

1 health or genetic services under subsection (f) or a genetic monitoring program under subsection
2 (g). These protections supplement GINA’s provisions on health plans and monitoring.
3

4 Subsection (h)(1) provides for reporting genetic test results to the employee when an
5 employment entity supplies testing. Not all individuals, however, wish to know their genetic
6 information; some may decide not to learn test results because of the psychological burdens that
7 may accompany such knowledge. So the draft also recognizes an employee’s right to decline to
8 know the results of a genetic test.
9

10 Subsection (h)(2) mandates the availability of genetic counseling so that the test results
11 can be interpreted for the employee if the test result is positive.
12

13 Subsection (h)(3) provides for destruction of the sample obtained for testing. The prompt
14 destruction of a sample obtained for genetic testing supplied by an employer protects the
15 employee’s privacy by preventing subsequent testing of the sample. It also recognizes, however,
16 that a testing laboratory is required to retain samples for certain time periods for certification
17 testing and other purposes. The provision follows statutes adopted in New Jersey and Oregon.
18

19 Possible alternative approaches (1) put the burden on the employee by requiring that the
20 sample be destroyed promptly on the request of the individual tested or (2) specify that a sample
21 may be retained for a period of time. Some provisions combine elements of more than one
22 approach. In New York, for example, a sample may be retained for ten years if authorized by the
23 individual from whom the sample was obtained. The Drafting Committee decided that the
24 placing the burden for destruction of the sample on the employment entity best protects an
25 employee’s privacy.
26

27 *Subsection (i) Forensic testing laboratories.* This subsection was added for consistency
28 with GINA. It allows a limited subset of employers – those that perform genetic testing for
29 identification for law enforcement purposes or to identify human remains – to collect DNA
30 samples from employees in order to check for contamination of samples with the employees’
31 DNA.
32

33 Testing under this subsection is not subject to the protections in subsection (h) because
34 testing for the purposes of quality control in an identification laboratory would be limited to the
35 sections of the genome used for identification, which are not thought to have any medical or
36 predictive significance.
37

38 *Subsection (j) Legal proceedings.* This subsection allows an employer to obtain an
39 employee’s genetic information that is relevant to a claim or defense in a legal proceeding,
40 through testing if necessary, if the employee places the employee’s health at issue in a legal
41 proceeding. It supplements GINA and provides standards that give an employee greater
42 protection than that afforded by civil litigation discovery standards for medical testing.
43

44 The employer’s ability to acquire genetic information under this subsection is limited in
45 that it applies only if the employer has satisfied the burden of proof to show compelling need and
46 that the information is otherwise unavailable. Only that portion of an employee’s genetic

1 information that is relevant to a claim or defense may be provided. These procedures provide
2 more protection than Rule 35 of the Federal Rules of Civil Procedure or state equivalents, which
3 provide that a court may order a physical examination on motion for good cause shown. The
4 Drafting Committee considered a requirement that the genetic test results be sealed or placed
5 under a protective order, but decided to leave this to existing law.
6

7 The substance of the subsection follows Utah’s statute, which authorizes genetic testing
8 when an employee has placed his or her health at issue in a proceeding, but only by order of a
9 court or administrative agency after finding compelling need and that the information is
10 otherwise unavailable. Utah Code Ann. § 26-45-103(2). Other states have more narrowly
11 authorized employer testing to investigate a workers’ compensation claim. (NH, NY).
12

13 *Employee susceptibility.* One circumstance in which the prior draft allowed genetic
14 testing is now omitted – genetic screening to determine the employee’s predisposing genetic
15 characteristics that may create susceptibility to harm to the employee from a workplace
16 condition. This was done based on the judgment that this provision would not provide greater
17 protection to employees than GINA, and would thus be preempted. This note is retained to alert
18 the Drafting Committee to this omission and to allow discussion, if desired, of the preemption
19 issue and the desirability of retaining this exception.
20

21 Several states currently allow to test for screening purposes, with the consent of the
22 employee. Iowa, Louisiana, New Hampshire, New York, and Wisconsin all have nearly identical
23 provisions that permit genetic testing of an employee to determine an employee’s susceptibility
24 to toxic substances if the employee requests testing, provides informed consent or authorization,
25 and the employer does not terminate the employee or take other adverse action as a result of
26 testing. Iowa Code Ann. § 729.6(7); N.H. Rev. Stat. § 141-H:3; N.Y. Exec. Law § 296; Wis.
27 Stat. Ann. § 111.372.
28

29 The utility of testing for susceptibility to workplace exposures is illustrated by chronic
30 beryllium disease. Beryllium is a lightweight metal used in many industries that poses the threat
31 of this disease when dust or fumes are inhaled. Industry protections have greatly reduced
32 exposure, but a small portion of the population can contract the disease even after a very brief
33 exposure. A genetic marker has reportedly been identified for this extreme sensitivity that
34 purports to show with certainty which individuals will contract beryllium disease and die from
35 short exposure. Cynthia Nance, Paul Miller, & Mark Rothstein, *Discrimination in Employment*
36 *on the Basis of Genetics*, 6 Employee Rights & Employment Policy Journal 57, 63-64 (2002). If
37 so, testing could provide information that could define an individual’s risk from workplace
38 exposure to beryllium.
39

40 Prior drafts allowed an employment entity to supply testing for such susceptibilities, but
41 provided that unless the employee volunteered the test results, the employment entity was not
42 authorized to obtain them.
43

44 *Safety of other employees.* The Drafting Committee considered, but did not adopt, a
45 provision that would permit employers to supply genetic testing in order to protect the safety of
46 other employees in the workplace. It would be very rare for a genetic marker to indicate a safety

1 threat to other employees with sufficient certainty to justify a genetic test. The draft does not
2 limit an employer's ability to take an employee's manifested medical condition into account for
3 safety purposes, subject to the provisions of the Americans With Disabilities Act.
4

5 **SECTION 203. EMPLOYEE AUTHORIZATION FOR ACQUISITION OF**
6 **GENETIC INFORMATION AND GENETIC TESTING.**

7 (a) Except as otherwise provided by law other than this [act], an employee's or
8 employee's family member's authorization for an employment entity's acquisition of the
9 individual's genetic information or a genetic test must be knowing and voluntary and indicated in
10 a record signed by the individual that complies with this section. An employment entity that
11 receives a valid authorization may use the genetic information or provide a test only in
12 accordance with the authorization. An authorization may not expand the acquisition or use of
13 genetic information or the genetic testing permitted by this [article] and it may not include
14 exculpatory language waiving any of the employee's or employee's family member's legal rights.

15 (b) An authorization for an employment entity to acquire an employee's or an employee's
16 family member's genetic information pursuant to Section 202(c), (f), or (g)(2)(B) must:

- 17 (1) describe the type of genetic information that will be acquired;
- 18 (2) describe the permitted uses of the genetic information;
- 19 (3) describe restrictions on disclosures of the genetic information; and
- 20 (4) state that the individual is entitled to a copy of the authorization.

21 (c) An authorization for an employment entity to provide a genetic test pursuant to
22 Section 202(f) or (g)(2)(B) must:

- 23 (1) describe the genetic test to be performed, its purpose, and the permitted uses of
24 the test result;
- 25 (2) inform the individual that only the authorized genetic test will be performed

1 on the individual's biological sample;

2 (3) explain the benefit of receiving genetic counseling before authorizing the test
3 and inform the individual that the employment entity is obligated to provide and, if the test is part
4 of a genetic monitoring program, pay for genetic counseling about the risks and benefits of the
5 test before the individual decides to authorize the test unless the individual waives genetic
6 counseling;

7 (4) inform the individual that the test result will be reported to the individual and a
8 health-care professional designated by the individual unless the individual directs otherwise;

9 (5) explain the benefit of receiving genetic counseling about the test result and
10 inform the individual that the employment entity is obligated to provide and, if the test is part of
11 a genetic monitoring program, pay for genetic counseling about the test result unless the
12 individual waives genetic counseling;

13 (6) include an opportunity for the individual to provide directions about reporting
14 test results and genetic counseling;

15 (7) inform the individual that the individual's biological sample will be destroyed
16 as soon as permitted by law after the test is completed unless the individual authorizes retention
17 of the sample or unless otherwise ordered by a tribunal;

18 (8) describe restrictions on disclosures of the test result; and

19 (9) state that the individual is entitled to a copy of the authorization.

20 (d) The use of the following forms complies with this section.

21
22 AUTHORIZATION FOR ACQUISITION OF GENETIC INFORMATION

23
24 I, _____, authorize _____ to acquire my
25 [print name] [name of employment entity]
26 genetic information as checked below. This information is provided:

- 1 for a voluntary genetic monitoring program conducted by _____.
- 2 [name of employment entity]
- 3 for _____, a voluntary program to that provides health and genetic services that
- 4 [name of program]
- 5 is offered by _____.
- 6 [name of employment entity]
- 7 by my voluntary submission for another purpose.

8

9

10 Family Medical History

11

12 Family medical history is information concerning diseases and disorders of family

13 members and other relatives. This information may be used for the following purposes:

14 _____.

15

16

17

18

19 My Genetic Test Results

20

21 Genetic tests are tests of DNA, RNA, chromosomes, or other material to determine

22 genetic characteristics. If _____ will provide the genetic

23 [name of employment entity]

24 tests, a separate authorization is necessary. The test results may be used for the following

25 purposes: _____.

26

27

28

29

30

31 Restrictions on Disclosure of Genetic Information. If this genetic information is provided for a

32 voluntary genetic monitoring program or a voluntary program to that provides health and genetic

33 services, only medical professionals involved in providing the program will have access to your

34 individual genetic information. Otherwise, _____ will not have

35 [name of employment entity]

36 access to your genetic information except in an aggregate form that will not identify you.

37

38

39 However, the genetic information may be disclosed to certain health researchers, to government

40 officials investigating compliance with laws protecting the privacy of genetic information or

41 prohibiting genetic discrimination, to a public health agency if the test result concerns a life-

42

43

44

45

46

1 threatening contagious disease, if expressly ordered by a court, or if you request and authorize a
2 disclosure.
3

4
5
6 By signing this authorization, you do not lose any legal rights to which you are entitled. You are
7 entitled to a copy of this authorization.
8
9

10
11 _____
12 Signature

_____ Date

13
14
15 **AUTHORIZATION FOR GENETIC TESTING**

16
17 Limited Authorization. Only the genetic tests that you authorize on this form will be
18 performed on your biological sample. These tests are voluntary.
19

20
21
22 Availability of Genetic Counseling. Before you complete this authorization, it is highly
23 recommended that you receive genetic counseling. Genetic counseling will help you assess your
24 risk for an inherited condition based on your family medical history and will help you understand
25 the options for prevention and management of genetic conditions. It will help you understand
26 and evaluate the risks, benefits, and consequences for you and your family of having the test(s)
27 listed below. _____ will provide [and pay for] this genetic counseling.
28 [Name of employment entity]
29
30
31

32
33
34
35
36 Proposed Genetic Tests. _____ proposes to provide the following
37 [Name of employment entity]
38 genetic tests:
39

40
41 _____
42 [Name of test]

43
44 This test is provided as part of a genetic monitoring program. The purpose of this test is
45 to monitor the effect of your exposure to _____. The result of the
46

1 [workplace condition]
2 test will be used only for the following purposes: _____.

3
4
5 _____
6 [Name of test]

7
8 This test is provided through _____ . The
9 [name of health or genetic services program]
10 purpose of the test is _____. The result will be used only for the
11
12 following purposes: _____.

13
14
15 Reporting Test Results and Genetic Counseling. The test results will be reported to you and
16
17 to a health-care professional whom you designate unless you direct otherwise. It is
18
19 recommended that you receive genetic counseling about the test results. Genetic counseling is
20
21 important for understanding the test results in the context of your medical and family history. It
22
23 can also provide you with support, informational resources, and referrals, as appropriate, that can
24
25 help you adapt to the implications of being at risk of a genetic condition. _____
26 [Name of employment entity]
27 will provide and [pay for] genetic counseling about the test results unless you decline genetic
28
29 counseling.

30
31
32 Restrictions on Disclosure of the Test Results. Other than the medical professionals involved in
33
34 providing this program, _____ will not have access to the test
35 [name of employment entity]
36 results of the individuals who authorize this test except in an aggregate form that will not identify
37
38 you. However, the test results may be disclosed to certain health researchers, to government
39
40 officials investigating compliance with laws protecting the privacy of genetic information or
41
42 prohibiting genetic discrimination, to a public health agency if the test result concerns a life-
43
44 threatening contagious disease, if expressly ordered by a court, or if you request and authorize a
45
46 disclosure.

1 Destruction of your Biological Sample. After the genetic test, your biological sample will be
2
3 destroyed as soon as permitted by law unless you authorize otherwise in writing or a court,
4
5 arbitral tribunal, or administrative agency requires retention of the sample.
6

7
8 By signing this authorization, you do not lose any legal rights to which you are entitled. You are
9
10 entitled to a copy of this authorization.
11

12
13 I, _____, authorize the genetic test(s) I have checked above.
14 [print name]

- 15
16 I wish to receive test results.
17 I do not wish to receive test results.
18
19 Report test results to the following health care professional:
20 Name: _____
21 Address: _____
22 Do not report test results to a health care professional.
23
24
25

26 _____
Signature

_____ Date

27
28
29 **Reporter's Notes**
30

31 This section sets forth an authorization requirement for genetic testing and certain
32 acquisitions of genetic information by an employment entity and specifies the elements that must
33 be contained in an authorization form. It applies to the situations in which Section 202 permits
34 an employment entity to acquire genetic information or conduct genetic testing with the consent
35 of the employee or employee's family member: providing genetic services as part of a wellnes
36 program, conducting a genetic monitoring program, and (for acquisition only) at the employee's
37 behest. This authorization requirement, coupled with statutory limits and duties imposed on
38 employment entities by the act, is designed to maintain privacy for genetic testing and genetic
39 information.
40

41 The prior draft included a broader requirement for authorization for acquisition of genetic
42 information and also included separate requirements for authorization for use, retention, and
43 disclosure of genetic information. In order to be more consistent with GINA, the Drafting
44 Committee decided to eliminate the detailed authorization requirements for any acquisition, use,
45 retention, and disclosure. The current draft combines the prior draft's provision for authorization
46 for genetic testing with the authorization requirements in GINA for acquisitions in connection

1 with wellness programs or genetic monitoring.
2

3 The term “authorization” is used instead of “informed consent” to avoid confusion with
4 the use of that term in medical practice. The section’s requirements for the content of an
5 authorization are more detailed and comprehensive than GINA. GINA requires employee
6 authorization when an employer acquires genetic information in connection with providing
7 health or genetic services and when an employer conducts a monitoring program that is not
8 required by law. In those circumstances, GINA requires an employee authorization that is “prior,
9 knowing, voluntary, and written.” In addition, the proposed GINA regulations also require that
10 the authorization be written so that the person from whom the genetic information is being
11 obtained is reasonably likely to understand the form; that the form describe the type of genetic
12 information that will be obtained and the general purposes for which it will be used; and that the
13 form describe the restrictions on disclosure of genetic information.
14

15 The Drafting Committee considered, but did not adopt, alternatives to authorization that
16 would (1) establish a general property right in a biological sample an individual provides for
17 genetic testing and in the resulting genetic information or (2) establish a limited property right in
18 genetic information applicable only to the context of employment.
19

20 *Subsection (a) Requirement for authorization for acquisition of genetic information and*
21 *for genetic testing.* Subsection (a) sets forth the basic requirements that authorization must be
22 knowing and voluntary and memorialized in a record. It limits an employment entity’s use of
23 genetic information and the tests it provides to those specified in the authorization and makes
24 clear that the authorization should not be interpreted to waive any of the employee’s rights.
25

26 When an employee is considering authorizing genetic testing, the employee should have
27 genetic counseling before signing the authorization in order to meet the requirement of this
28 subsection that an authorization is knowing and voluntary. Genetic counseling provides
29 employees with adequate information to make an informed decision about genetic testing. It also
30 makes them aware of their options regarding reporting of test results and help in interpreting
31 them through genetic counseling. An employment entity that offers a genetic test as part of a
32 health program or genetic monitoring program has an obligation to provide genetic counseling
33 under Section 202. Genetic counseling may be provided by a genetic counselor, but may also be
34 provided by a qualified physician or geneticist. An employee may waive genetic counseling, but
35 must first be made aware of the benefits of genetic counseling.
36

37 The power to authorize inherently and of necessity includes to power to revoke and the
38 employee may revoke this authorization at any time.
39

40 The Drafting Committee anticipated that there might be circumstances in which an
41 individual is incapacitated or incapable of authorizing a genetic test. Other law of the state may
42 provide for a substitute decisionmaker or signer for the authorization if the employee is
43 incapacitated or incompetent. Revocation of an authorization by a substitute is similarly left to
44 existing law of the state that governs power of attorney, guardianship, or other substitute decision
45 makers.
46

1 *Subsection (b) Content of authorization for acquisition of genetic information.* This
2 subsection follows the GINA requirements for authorization for acquisition of genetic
3 information and is consistent with the proposed implementing regulations.
4

5 *Subsection (c) Content of authorization for genetic testing.* Before any genetic testing
6 can be performed, unless the testing is required by law, an employee must affirmatively authorize
7 the genetic testing and the employment entity’s acquisition of the resulting genetic information.
8 Section 202 limits the situations in which employment entities may request authorization for
9 testing from employees: an employment entity may supply genetic tests as part of health or
10 genetic services, but only with prior authorization from the employee, and as part of a genetic
11 monitoring program, but only if required by law or with prior authorization from the employee.
12

13 This subsection builds on the GINA requirements for authorization for acquisition of
14 genetic information so that it applies to the situation when that acquisition involves offering a
15 genetic test. It draws on N.Y. Civ. Rights Law § 79-1 (McKinney), which establishes
16 requirements for consent for a genetic test.
17

18 The requirements in subsection (c)(3), (5), and (6) reflect the obligations of the
19 employment entity to provide genetic counseling under Section 202(f), (g), and (h).
20

21 The notification provision for retention of the sample in (c)(7) is consistent with the
22 employment entity’s obligation to ensure that the sample is destroyed under Section 202(h),
23 which recognizes that the testing laboratory may be required to retain the sample for certification
24 purposes.
25

26 *Subsection (d) Authorization form.* The use of a form following the pattern in this
27 subsection would comply with the requirements of the section. This subsection provides
28 guidance to employers on appropriate content for a form. The Drafting Committee previously
29 decided that it preferred having the forms in the black-letter law instead of in the comments.
30

31 **SECTION 204. PROHIBITION ON USE OF GENETIC INFORMATION.**

32 (a) An employer may not take an adverse employment action against an employee based
33 on the employee’s genetic information, including but not limited to failing or refusing to hire,
34 discharging, or discriminating against an employee in regard to compensation, terms, conditions,
35 or privileges of employment.

36 (b) An employment agency may not take an adverse employment action against an
37 individual based on the individual’s genetic information, including but not limited to failing or
38 refusing to refer an individual for employment or discriminating against an individual.

1 (c) A labor organization may not take an adverse employment action against a labor
2 organization member based on the member's genetic information, including but not limited to
3 excluding or expelling a labor organization member from membership in the organization or
4 discriminating against any labor organization member.

5 (d) An employer, labor organization, or joint-labor management committee controlling an
6 apprenticeship or a training or retraining program may not take an adverse employment action
7 against an individual based on the individual's genetic information, including but not limited to
8 discriminating against an individual in admission to or employment in the program.

9 (e) A credentialing authority may not take an adverse employment action against an
10 individual based on the individual's genetic information, including but not limited to
11 discriminating against an individual in the provision of credentials.

12 (f) An employment entity may not limit, segregate, or classify an individual, or fail or
13 refuse to refer for employment an individual, in a way that would deprive or tend to deprive the
14 individual of employment opportunities or otherwise adversely affect the status of the individual
15 as an employee based on the individual's or the individual's family member's genetic
16 information.

17 (g) An employment agency, labor organization, joint labor-management training or
18 apprenticeship program, or credentialing authority may not cause or attempt to cause an employer
19 to discriminate against an employee in violation of this [article].

20 (h) An employment entity may not discriminate against an employee because the
21 employee has opposed an act or practice in violation of this [article] or because the employee
22 made a charge, testified, assisted, or participated in any manner in an investigation, proceeding,
23 or hearing under this [article].

Reporter's Notes

This section is based on the anti-discrimination provisions in GINA, supplemented with the provision from the prior ULC draft that prohibits employment entities from taking any adverse employment action based on genetic information. GINA has a separate statutory section defining unlawful employment practices for each type of employment entity. This version follows the proposed EEOC regulations, which consolidate the provisions as much as possible, using the terminology of GINA.

GINA does not contain the provision on retaliation in subsection (h), but the EEOC has added it into the regulations. This omission from the statute illustrates the dangers of enumerating adverse employment actions. Subsection (e) governing credentialing authorities is another departure from GINA. Both additional provisions provide employees greater protection.

Prohibition of adverse employment decisions. The act's prohibition of adverse employment decisions based on genetic information is consistent with GINA and is included to make sure that employee protections are not limited by omission of an employment actions from the list in GINA. "Adverse employment decision" is a term of art in employment law that the Drafting Committee decided does not need to be defined in this act. The term should be interpreted broadly. One example of a broad statement of adverse employment actions can be found in the District of Columbia Human Rights Act, which makes it a discriminatory practice for an employer "[t]o fail or refuse to hire, or to discharge, any individual; or otherwise to discriminate against any individual, with respect to his compensation, terms, conditions, or privileges of employment, including promotion; or to limit, segregate, or classify his employees in any way which would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect his status as an employee." D.C. Code § 2-1402.11.

Rationale for limiting actions of employment entities. The restrictions on employment actions in GINA and this draft are important because they will dispel uncertainty about how courts would otherwise apply federal statutes to decisions based on genetic information that predicts employee susceptibility to harm from workplace exposures. On one hand, in 1991 the United States Supreme Court held that a chemical company's policy barring women of child-bearing age from employment opportunities that involved exposure to lead violated Title VII prohibitions on gender discrimination. *International Union v. Johnson Controls*, 499 U.S. 187 (1991). On the other hand, the ADA allows employers to act on health information, even in the case of disability, when there is a direct threat to the health or safety of others in the workplace. The Equal Employment Opportunity Commission (EEOC) has interpreted this ADA provision to apply when there is no risk to others but when an employer can show that an individual's disability poses a significant risk of harm to the individual. The United States Supreme Court upheld this interpretation. *Chevron v. Echazabal*, 122 S. Ct. 2045 (2002). Although the *Echazabal* case did not involve a genetic characteristic, but rather a worker's liver damage due to exposure to workplace solvents, the implication of the case is that in the absence of a prohibition in a state statute, an employer may make adverse employment decisions based on genetic screening or monitoring requested by an employee even if there is no threat to others. Section 204 does not permit an employer to take an adverse employment action under these circumstances. Harm to the employee or to others is not a justification. As a result, employers

1 would not be able to use an employee’s genetic information in the way the employee’s health
2 information was used in the *Echazabal* case.

3
4 Note that the section does not necessarily prevent an employer from making decisions
5 based on the effects of an employee’s manifest genetic condition or disease in the workplace.
6 This is because the protections in this section involve the use of “genetic information,” which is
7 defined with reference to a “genetic test.” In addition, Section 209 makes clear that employment
8 entities may acquire and use medical information about a manifested disease, even one with a
9 genetic basis, if that medical information is not genetic information. In addition to the
10 protections of this section, some employees with manifest genetic conditions would be covered
11 under the ADA if the condition limits a major life activity. But there is no comprehensive
12 protection for individuals with medical conditions that result from genetic traits. While some
13 maintain that attempts to prevent genetic discrimination are mostly meaningless without
14 protection for people who have genetic diseases, *see* Mark A. Rothstein, *Genetic Privacy and*
15 *Confidentiality: Why They are so Hard to Protect*, 26 J. L. Med. & Ethics 181 (1998), others
16 emphasize the difficulties with either policy choice, *see* Henry T. Greely, *Genotype*
17 *Discrimination: The Complex Case for Some Legislative Protection*, 149 U. Pa. L. Rev. 1483,
18 1503 (2001).

19
20 *Existing state law.* Many state statutes limit use of genetic information by prohibiting
21 discrimination among employees or applicants for employment on the basis of genetic
22 information. (Ark, Ill, Kan, LA, Maine, MD, Mass, Mich, MO, Neb, Nev, NJ, NY, NC, OK,
23 OR, RI, SD, Tex). These statutes do not all provide protections as comprehensive as those in
24 GINA and this act. Other states more generally ban any use of genetic information in
25 employment. For example, New Mexico’s 2005 statute provides simply that “[i]t is unlawful for
26 a person to use genetic information in employment,” In Utah, employers may not take into
27 account genetic information about an individual in connection with an employment decision.
28 Similarly, in Iowa, an employer may not use genetic information to “affect the terms, conditions,
29 or privileges of employment” of a person who gets a genetic test. Iowa Code Ann. § 729.6(2).
30 Minnesota and Wisconsin prohibit adverse employment actions based on genetic information.
31 Minn. Stat. § 181.974 subd. 2(a)(2) (may not “affect the terms or conditions of employment or
32 terminate the employment of any person based on protected genetic information”); Wis. Stat. §
33 111.375 (may not “affect terms, conditions or privileges of employment, labor organization
34 membership or licensure or terminate the employment or labor organization membership or
35 licensure”).
36

37 **SECTION 205. AUTHORIZED USE OF GENETIC INFORMATION.**

38 (a) An employment entity that obtains genetic information as permitted by Section 202
39 may use the genetic information for purposes authorized by law, including:

40 (1) to provide health or genetic services to an employee or employee’s family
41 member;

1 (2) to monitor the effects of an employee’s exposure to a workplace condition as
2 part of a genetic monitoring program;

3 (3) for purposes of quality control if the employer conducts DNA analysis for law
4 enforcement purposes as a forensic laboratory or for purposes of identifying human remains; or

5 (4) to defend a claim in a proceeding before a tribunal in which an employee has
6 placed the employee’s health at issue.

7 **Reporter’s Notes**

8
9 The draft selectively authorizes ways that an employment entity may use genetic
10 information. It is taken from the prior draft and clarifies GINA, which permits employers to
11 acquire information for certain purposes, but fails to authorize those uses.

12
13 The Drafting Committee considered a provision that would have allowed adverse
14 employment actions in the case of an employee with a predisposing genetic characteristic that
15 poses a direct threat of harm to others. It decided not to include this provision because the
16 Drafting Committee was unable to identify any known genetic trait that would qualify and if
17 testing is permitted for this purpose it could be abused. In addition, such a provision would
18 probably be preempted by GINA, which permits states to depart from federal law only to provide
19 greater protections for employees.

20
21 Because of concerns about preemption, this draft does not include a provision from prior
22 drafts that would have permitted an employer to use genetic information on employee
23 susceptibility to harm in the workplace to reduce the potentially harmful exposure, but not to
24 make an employment decision that would adversely affect the employee. The utility of this form
25 of genetic information is described in the Reporter’s Notes to section 202.

26
27 **SECTION 206. ACCESS TO GENETIC INFORMATION BY EMPLOYEE.** An
28 employee may inspect, request correction of, or obtain a copy of the employee’s genetic
29 information in any record of an employment entity which contains the information. If an
30 employee requests correction of genetic information in a signed record, the employment entity
31 shall make the correction if justified.

32 **Reporter’s Notes**

33
34 This section supplements GINA and is more protective of the employee than the federal

1 statute. GINA allows employment entities to provide an employee’s genetic information to the
2 employee as an exception to its general prohibition on disclosure, but it does not give an
3 employee a right to obtain this information. This section is based on the conclusion that an
4 employee ought to be able to find out what genetic information an employer knows about an
5 employee and to have the same information. It is modeled on 16 Del. Code § 1223.
6

7 This section also provides a mechanism for an employee to correct genetic information
8 contained in employer records. The right to correct genetic information also includes
9 expungement of information that should not be in a particular record. For example, an employer
10 may have incorrectly placed genetic information in an employee’s personnel file instead of
11 segregating it as required by Section 207.
12

13 If the employer supplied the genetic testing, information may also be kept in files at the
14 laboratory that performed the testing. The employer’s responsibility to correct errors does not
15 extend to the testing laboratory, which is regulated under the Clinical Laboratory Improvement
16 Amendments, (CLIA), 42 U.S.C. § 263a.
17

18 The Drafting Committee considered but rejected an exception that would have prohibited
19 employee access to information an employment entity has compiled for litigation. This situation
20 will be governed by normal discovery rules, which are unaffected by this section.
21

22 **SECTION 207. CONFIDENTIALITY AND RETENTION OF GENETIC**
23 **INFORMATION.**

24 (a) An employment entity shall treat an employee’s genetic information as a confidential
25 record.

26 (b) If an employment entity possesses an employee’s genetic information, the
27 employment entity shall keep the genetic information in a record separate from the employee’s
28 personnel file.

29 (c) The requirements of subsection (b) are satisfied if the employment entity keeps the
30 genetic information in the record in which it maintains confidential medical information subject
31 to section 102(d)(3)(B) or the Americans with Disabilities Act, 42 U.S.C. § 12112(d)(3)(B).

32 (d) Notwithstanding this section, an employment entity may retain genetic information
33 obtained in aggregate form pursuant to Section 202(f) for use in providing health or genetic

1 services and Section 202(g) for use in a genetic monitoring program.

2 **Reporter’s Notes**

3
4 *Subsection (a) Confidentiality.* This subsection declares that genetic information, which
5 includes family medical history, is confidential in the employment context. “Genetic
6 information” is a category that includes information about use of or request for genetic services,
7 so this section also protects an employee’s authorizations concerning genetic tests or information.
8 This subsection is consistent with GINA, which provides that genetic information shall be treated
9 as a confidential medical record.

10
11 *Subsection (b) Retention of genetic information.* This provision follows the approach of
12 GINA and operates if an employer “possesses” genetic information. It does not require an
13 employee to authorize retention of the information. The protections apply to any genetic
14 information maintained by the employment entity. They are not limited by the manner in which
15 the employment entity obtained the genetic information and they apply to any genetic
16 information from any source, even if the acquisition was inadvertent.

17
18 Employment entities may retain genetic information without the burden of obtaining
19 employee authorization to maintain the information. They must protect the employee’s privacy,
20 however, by maintaining it as confidential information and by segregating this information from
21 the employee’s personnel file.

22
23 *Subsection (c) Coordination with the Americans with Disability Act.* This provision
24 follows GINA. There is a need for coordination because many employers will acquire genetic
25 information when they acquire an employee’s medical records (which they may request under the
26 ADA after a conditional offer of employment or during employment for job-related purposes).
27 Genetic information is likely to be interspersed throughout medical records and an employer that
28 requests medical information is likely to receive an entire file, including genetic information.
29 GINA addresses this by allowing employers to keep genetic information with confidential
30 medical information acquired under the ADA so long as both types of information are retained as
31 confidential records.

32
33 *Subsection (d) Aggregate information for wellness or genetic monitoring programs.*
34 Under Section 202, an employment entity is allowed to acquire genetic information for the
35 operation of a wellness program or a genetic monitoring program, but only in an aggregate form
36 that does not identify individual employees. This subsection correspondingly allows an
37 employment entity to retain, and Section 208(d) allows it to disclose, this aggregate genetic
38 information. Retention and disclosure of aggregate information may be necessary in order to
39 analyze trends or take action to reduce risk in the workplace.
40

41 **SECTION 208. DISCLOSURE OF GENETIC INFORMATION.**

42 (a) Except as otherwise permitted in this section, an employment entity may not disclose

1 an employee's or employee's family member's genetic information.

2 (b) An employment entity may disclose an employee's or employee's family member's
3 genetic information:

4 (1) to the employee or, if the genetic information is the employee's family
5 member's, to the employee's family member and to a health-care professional designated by the
6 employee or employee's family member at the written request of the employee or employee's
7 family member;

8 (2) at the request of the employee or, if the genetic information is the employee's
9 family member's, the employee's family member, to a person the employee or employee's family
10 member has authorized to receive the genetic information in a knowing and voluntary
11 authorization indicated in a record signed by the employee or the employee's family member;

12 (3) to an occupational or other health researcher if the research is conducted in
13 compliance with the regulations and protections provided for under part 46 of title 45, Code of
14 Federal Regulations;

15 (4) in response to an order by a tribunal, if disclosure of the genetic information is
16 expressly authorized by the order;

17 (5) to government officials who are investigating compliance with this [act] or
18 with the Genetic Information Nondiscrimination Act, 42 U.S.C. § 2000ff to 2000ff-11, if the
19 information is relevant to the investigation;

20 (6) to the extent the disclosure is made to comply with the certification provisions
21 of the Family Medical Leave Act, 29 U.S.C. § 2613, or the [state family and medical leave act];

22 (7) to a public health agency when the genetic information concerns the
23 manifestation in an employee or an employee's family member of a contagious disease that

1 presents an imminent hazard of death or life-threatening illness; or

2 (8) in aggregate form in connection with health or genetic services provided
3 pursuant to Section 202(f) or a genetic monitoring program operated pursuant to Section 202(g).

4 (c) The employment entity shall provide notice in a record to the employee whose genetic
5 information is disclosed if:

6 (1) the disclosure is made under subsection (b)(4) of this section and the tribunal's
7 order was secured without the knowledge of the employee; or

8 (2) the disclosure is made under subsection (b)(7) of this section.

9 **Legislative Note:** *In subsection (b)(6), states should insert for [state family and medical leave*
10 *act] the appropriate name for the state's act.*

11 **Reporter's Notes**

12
13
14 This section follows the format of GINA, which contains a general prohibition on
15 disclosure of genetic information by employers coupled with exceptions. It supplements GINA
16 by permitting disclosures at the request of the employee.

17
18 *Existing state law.* A number of states that have enacted (1) general privacy protections
19 for genetic information that prohibit disclosure without informed consent or authorization
20 (Alaska, Cal, Del, Fla, Maine, Mass, Nev, NH, NJ, NMex, NY, OR) or (2) specific protections
21 against the disclosure of genetic information by employers (Ariz, Fla, LA, Mass, NH, NJ, Or,
22 RI).

23
24 *Subsection (a) General prohibition on disclosure of genetic information.* This subsection
25 follows GINA and establishes a blanket rule that employment entities may not disclose
26 employee's genetic information, subject to limited exceptions.

27
28 *Subsection (b) Permitted disclosures.* This subsection sets forth the circumstances under
29 which an employer may disclose an employee's genetic information.

30
31 Subsection (b)(1) permits an employment entity to disclose genetic information to the
32 individual whom it concerns. This is consistent with the employee's right of access to the
33 employee's genetic information established by Section 206. GINA includes a parallel provision.

34
35 Subsection (b)(2) goes beyond GINA and respects employee autonomy by providing for
36 disclosures to third parties when an employee requests the disclosure and provides a knowing
37 and voluntary authorization. The power to authorize inherently and of necessity includes to
38 power to revoke and the employee may revoke this authorization at any time.

1 Other law of the state may provide for a substitute decisionmaker or signer for the
2 authorization if the employee is incapacitated or incompetent. Revocation of an authorization by
3 a substitute is left to existing law of the state that governs power of attorney, guardianship, or
4 other substitute decision makers.
5

6 As a matter of good business practice, an employment entity should retain an employee's
7 authorization for disclosure of genetic information. An authorization for disclosure of genetic
8 information contains genetic information and so should be kept separately from the employee's
9 personnel file.
10

11 Subsection (b)(3) is taken from GINA and permits disclosures to occupational and health
12 researchers.
13

14 Subsection (b)(4) is taken from GINA and permits disclosures in response to an order
15 from a court, arbitral tribunal, or administrative agency. Disclosure of genetic information is
16 limited to genetic information explicitly included in the terms of the order. The provision does
17 not authorize other disclosures in connection with litigation such as in response to a discovery
18 request, unless ordered by the tribunal. Subsection (c)(1) requires the employer to give the
19 employee notice of this disclosure if the tribunal's order was issued without the employee's
20 participation in the proceeding.
21

22 Subsection (b)(5) is taken from GINA and permits disclosures to government officials
23 investigating compliance with the act or with GINA.
24

25 Subsection (b)(6) is taken from GINA and permits disclosures made in conjunction with
26 the Family Medical Leave Act or state or local leave law.
27

28 Subsection (b)(7) is taken from GINA and permits disclosure of genetic information to
29 public health authorities in connection with a contagious disease that creates an imminent threat
30 of death or life-threatening illness. If a disclosure is made under this subsection, the employer
31 must provide notice to the employee under subsection (c).
32

33 Subsection (b)(8) permits disclosures of aggregate genetic information obtained as part of
34 a health or genetic services program or a genetic monitoring program under Section 202. This
35 provision supplements GINA.
36

37 *Subsection (c) Notice to employee of disclosures.* These limited requirements that an
38 employment entity provide notice to an employee of disclosure of genetic information are taken
39 from GINA.
40

41 **SECTION 209. MEDICAL INFORMATION THAT IS NOT GENETIC**

42 **INFORMATION.** An employment entity's acquisition, use, retention, or disclosure of medical
43 information that is not genetic information about a manifested disease, disorder, or pathological

1 condition of an employee does not violate this [article] even if the manifested disease, disorder,
2 or pathological condition has or may have a genetic basis.

3 **Reporter’s Notes**
4

5 This section is a paraphrase of section 210 of GINA, 42 U.S.C. § 2000ff-9. It is meant to
6 signal that medical information about a manifested disease is not covered by the act if it is not
7 genetic information, but that medical information is covered if it is genetic information. For
8 example, an individual with breast cancer might learn from genetic testing that she is positive for
9 a BRACA mutation and thus has an increased risk of ovarian cancer. Under this section, the fact
10 that she has breast cancer is not protected, but information about the genetic mutation is
11 protected.
12

13 Under this section an employment entity does not violate the act when it acquires, uses,
14 retains, or discloses medical information about a manifest disease that is not genetic information.
15 However, that information may be protected by HIPAA or the ADA.
16

17 **SECTION 210. RELATIONSHIP TO HEALTH PRIVACY REGULATIONS.** This
18 [article] does not apply to genetic information that is protected health information subject to the
19 regulations issued by the Secretary of Health and Human Services pursuant to section 264(c) of
20 the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d-2 note.

21 **Reporter’s Notes**
22

23 This is a new section in this draft. It concerns the interaction of provisions when an
24 employment entity is also a covered entity under HIPAA. The section makes clear that when a
25 covered entity obtains information that is protected health information under the HIPAA Privacy
26 Rule, the entity is governed by the HIPAA rule. For example, if a hospital’s employee becomes a
27 patient, the hospital’s acquisition and use of that patient’s genetic information is governed by the
28 HIPAA privacy rule, not GINA or this act.
29

30 The language of this section follows the proposed EEOC regulation implementing GINA,
31 29 CFR § 1635.11(d). GINA section 206, 42 U.S.C. § 2000ff-5, takes a slightly different
32 approach. It provides that the employment provisions of GINA shall not prevent a covered entity
33 under HIPAA from any use or disclosure of health information that is authorized by the
34 regulations issued pursuant to HIPAA. The Drafting Committee should consider whether to
35 retain the language of the regulations or use the GINA formulation.
36

37 The GINA regulations also contain a reference to this exclusion from their scope in the
38 regulation on confidentiality and disclosure. This states that “nothing in the regulations shall be
39 construed to apply to the use or disclosure of genetic information that is protected health

1 information subject to the regulations issued pursuant to [HIPAA]. 29 CFR § 1635.9(c)
2 (proposed). The Drafting Committee may want to consider adding parallel language to the act’s
3 sections on use and disclosure. For example, a subsection could be added to Section 208 that
4 would state: “Nothing in this section shall apply to the disclosure of protected health information
5 that is subject to the regulations issued pursuant to section 264(c) of the Health Insurance
6 Portability and Accountability Act of 1996, 42 U.S.C. § 1320d-2 note.”
7

8 **SECTION 211. REMEDIES; LIMITATION OF ACTIONS.**

9 (a) A violation of this [article] creates a private cause of action on behalf of the aggrieved
10 party for money damages or other relief. An individual may seek remedies provided by law other
11 than this [act], but exhaustion of administrative remedies is not required before seeking relief for
12 a violation of this [article].

13 (b) A tribunal shall award a prevailing employee reasonable attorney’s fees and costs
14 unless justice requires otherwise.

15 (c) An individual may file an action authorized in subsection (a) not later than two years
16 after the individual discovers the violation of this [article] or an individual exercising reasonable
17 care should have discovered the violation. This limitations period may not be reduced by
18 agreement between an employment entity and an employee. If an individual seeks remedies
19 provided by law other than this [act], this limitations period shall be tolled during the pendency
20 of administrative proceedings pursuant to that law. This subsection does not alter [tort claims
21 notice provisions].

22 *Legislative Note: In subsection (c), the state should insert for [tort claims notice provisions] a*
23 *reference to the state statute that governs the notice provisions that are required for tort claims*
24 *against the state.*
25

26 **Reporter’s Notes**

27
28 For private employees, GINA adopts the enforcement and remedy structure of Title VII of
29 the Civil Rights Act of 1964, incorporating it by reference. For the other employee groups it
30 covers – state, federal, and congressional employees – GINA incorporates the slightly different
31 remedy provisions of the other relevant federal EEO statutes. GINA explicitly excludes,

1 however, claims for disparate impact, a cause of action for unintentional discrimination that is
2 available under Title VII.
3

4 This section provides remedies that are more protective of employees than those available
5 under GINA. This follows the pattern of many of the state EEO statutes that supplement Title
6 VII and other federal civil rights statutes. The section provides a private cause of action that can
7 be filed without exhausting administrative remedies and hence does not increase the burden on
8 state fair employment agencies. It establishes a two-year statute of limitations. An aggrieved
9 person also has the option to use the federal administrative apparatus and may pursue relief
10 through state administrative avenues, if applicable, so the section provides a tolling provision for
11 the statute of limitations during that time period. As in the federal EEO statutes, the section
12 provides for fee shifting for prevailing employees to compensate for their cost to enforce the
13 statute.
14

15 *GINA's administrative procedures and the federal private cause of action.* Under Title
16 VII, and hence by reference under GINA, if there is a state or local fair employment practice
17 agency that is designated as a "deferral agency," an individual seeking relief from employment
18 discrimination must first file a charge with that agency and the EEOC must defer jurisdiction
19 over the complaint for 60 days or until the state agency has terminated its action. Almost all the
20 states have created agencies that qualify as deferral agencies under Title VII.
21

22 If there is no qualifying state fair employment practices agency, a complainant has 180
23 days from the violation to file a discrimination charge with the EEOC. When a state has a
24 deferral agency, then a complainant must meet the state filing deadline but has 300 days to file
25 with the EEOC but a complainant must also meet the state's time limitation for filing an
26 administrative claim. State time limitations range from 90 days (2 states) to one year (9 states),
27 with a majority of states (31) setting the time limit at 180 days or 6 months. The EEOC and state
28 fair employment agencies enter into annual work sharing agreements that provide that when a
29 charge is filed with either the EEOC or the state agency it is treated as dual filed with both of
30 them.
31

32 The EEOC serves a notice on the person named in the charge and investigates the charge.
33 If it finds reasonable cause to pursue the complaint, it must attempt to conciliate the matter. If
34 the EEOC dismisses the case, or if settlement is not reached within 180 days from the time the
35 charge was filed and the EEOC and Attorney General decide not to bring a court case, the EEOC
36 issues a "right to sue letter." An employee may take court action only after the EEOC issues this
37 notice. The case must then be filed in court within 90 days.
38

39 Filing a timely administrative charge with the EEOC is a jurisdictional prerequisite to
40 filing a suit under Title VII, *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 978 (1973), and
41 courts in a number of states have similarly interpreted statutes creating fair employment practice
42 agencies to require exhaustion of state administrative remedies before a plaintiff may bring a
43 private cause of action in state court. *See, e.g., Strauss v. A.L. Randall Corp.*, 194 Cal. Rptr. 520,
44 524 (Cal. Ct. App. 1983); *Melley v. Gillette Corp.*, 491 N.E.2d 252 (Mass. 1986); *Bonham v.*
45 *Dresser Indus.*, 569 F.2d 187 (3d Cir. 1977) (construing Pennsylvania Human Rights Act).
46

1 *Subsection (a) Private cause of action.* This subsection authorizes a private cause of
2 action for violation of the employment article of the act. An aggrieved person may choose to use
3 GINA’s administrative remedies, including filing with a state agency, but unlike under GINA is
4 not required to do so. This elimination of the requirement for exhaustion of administrative
5 remedies is consistent with statutory provisions in 17 states (as of 2005), in which private EEO
6 causes of action may be brought without first filing a charge with an administrative agency.
7 (Alaska, Arkansas, District of Columbia, Idaho, Kentucky, Louisiana, Maine, Minnesota, New
8 Jersey, New York, North Dakota, Ohio, Oregon, Tennessee, Vermont, Virginia, Washington)
9

10 Given the privacy interests at stake with genetic information, there are special reasons for
11 allowing a private cause of action without requiring exhaustion of administrative procedures.
12 While state employment discrimination agencies have the expertise and the apparatus in place to
13 enforce state civil rights and disability statutes, discrimination agencies do not have expertise in
14 privacy violations and the typical remedies for employment discrimination are not necessarily
15 appropriate for a privacy violation. Enforcement could be turned over to an agency with that
16 expertise, but the Drafting Committee wish to avoid the cost of creating and funding a new
17 agency. Moreover, the Drafting Committee did not want to impose the delay associated with
18 administrative processes on an aggrieved employee.
19

20 *Subsection (c) Statute of limitations and tolling.* Subsection (c) establishes a limitations
21 period of two years to file an action for a violation of the act’s employment article. This
22 compares to state statutes of limitations for fair employment actions that range from six months
23 (Colorado) to six years (Ohio), with many states providing for two years (*e.g.* NJ) or three years
24 (*e.g.* Michigan, NY, Washington).
25

26 The subsection also provides that the limitations period may not be reduced by agreement
27 of an employment entity and an employee. This provision is included because some employers
28 have adopted a practice of inserting into applications for employment an agreement for six
29 months statutes of limitations for claims related to employment, along with a waiver of any
30 contrary limitation. *See* Joel C. Tuoriniemi & Roger W. Teinsch, *Return to Camelot: A Statutory*
31 *Model for Judicial Examination of Employment Agreements with Shortened Periods of*
32 *Limitations*, 35 Ohio N.U. L. Rev. 751 (2009). Some courts have enforced these contractual
33 limitation periods, including in civil rights actions, reasoning in part that contractual
34 modifications of limitation periods for these claims are not explicitly prohibited by statute. *See,*
35 *e.g., Clark v. Daimler Chrysler Corp.*, 706 N.W.2d 471 (Mich. Ct. App. 2005) (substitution of 6-
36 month limitation period for Michigan’s statutory 3-year statute of limitations for a state age
37 discrimination claim); *Thurman v. Daimler Chrysler Corp.*, 397 F.3d 352 (6th Cir. 2004) (same
38 for both state and Title VII race discrimination claim). The explicit prohibition in this subsection
39 is designed to prevent courts from enforcing shorter limitations periods in employment
40 applications or contracts for the private cause of action provided in this section.
41

42 The subsection provides that the statute of limitations shall be tolled during
43 administrative proceedings on a claim if an aggrieved person opts to pursue administrative
44 remedies. This provision avoids the risk that an administrative agency may fail to terminate a
45 claim or issue a right-to-sue letter in a timely fashion and eliminates the need for a plaintiff to file
46 a cause of action as a precautionary measure while pursuing administrative relief. The courts

1 should not be relied upon to toll a statute of limitations for the completion of administrative
2 proceedings on an employment discrimination claim. *See, e.g., Barczak v. Rockwell Int'l Corp.*,
3 68 Mich. App. 759, 244 N.W.2d 24 (Mich. Ct. App. 1976) (refusing to toll statute of limitations
4 for state claim of sex discrimination when complaint was filed with state Civil Rights
5 Commission).

6
7 Finally, subsection (c) makes clear that when an action is brought against a state employer
8 under this section the limitation period provided in this subsection does not alter a state's notice
9 requirements for tort claims brought against the state.

10
11 *GINA's remedies and damages.* Title VII authorizes courts to issue injunctive relief and
12 to order affirmative action as appropriate. This may include, but is not limited to, reinstatement
13 or hiring of employees, with or without back pay, and any other equitable relief the court finds
14 appropriate, such as promotion and front pay. Back pay may not extend for more than two years
15 prior to the date the charge was filed with the EEOC, and it is offset by interim earnings or
16 amounts that were earnable with reasonable diligence by the aggrieved individual. For
17 intentional discrimination, the Civil Rights Act of 1991 added compensatory and punitive
18 damages to the remedies available under Title VII. Punitive damages are available if the
19 defendant acted with malice or reckless indifference to the employee's federally protected rights,
20 but are not available against federal, state, or local government employers. There is a cap on the
21 total amount that may be awarded in punitive damages and compensatory damages for
22 nonpecuniary and future pecuniary losses. The cap is graduated based on employer size as
23 measured by the number of employees:

24

Number of employees	Cap on compensatory and punitive damages
more than 14 & less than 101	\$ 50,000
more than 100 & less than 201	\$ 100,000
more than 200 & less than 501	\$ 200,000
more than 500	\$ 300,000

25

26
27
28
29
30
31 Prevailing parties may be awarded a reasonable attorney's fee as part of litigation costs. GINA
32 differs from Title VII, however, in that it excludes remedies for claims of disparate impact,
33 subject to future study by a Commission.

34
35 *Remedies and damages under the Uniform Act.* The employment article of the act is
36 intended to provide remedies for privacy violations, employment determinations based on misuse
37 of genetic information, and other harms. Privacy violations involve acquisition, retention, or
38 disclosure of genetic information that does not comply with the Act. Employment
39 determinations could include failure to license, hire, refer for employment, promote, or decisions
40 to terminate, demote, reduce pay, reassign, or to take any other adverse action. Other harms
41 could include torts such as intentional infliction of emotional distress. The appropriate remedy
42 will vary with the type of violation.

1 The prior draft provided a right to jury trial and specified that compensatory damages,
2 back pay, front pay, reassignment, reinstatement, injunctive relief, punitive damages, and
3 expungement of records are available remedies for a violation of the article. This draft mor
4 simply authorizes a private cause of action for “money damages or other relief.” It also
5 authorizes fee and cost shifting to compensate prevailing employees for the cost of enforcing the
6 statute.

7
8 The broad availability of remedies under the act follows the general approach of state fair
9 employment practices acts. Prior to the availability of compensatory and punitive damages under
10 federal law pursuant to the Civil Rights Act of 1991, many states provided for these damages
11 either as agency remedies, court remedies, or both. Compensatory damages have typically been
12 defined to include coverage for emotional distress, mental anguish, pain, suffering, humiliation,
13 and the like. When punitive damages are available, the plaintiff usually must show that the
14 defendant acted with malicious or intentional disregard for statutory rights. Attorney’s fees and
15 costs are generally available under state fair employment practices acts.

16
17 The section does not increase the enforcement burden on state agencies. The primary
18 remedy for a violation of the article is a private civil action. Fee and cost shifting are included to
19 compensate prevailing employees for their costs to enforce the statute.

20
21 The act differs from provisions in several states that specify statutory damages. A privacy
22 rights perspective assumes an intrinsic harm from the invasion of privacy, whether or not
23 consequential damages are incurred. Because of difficulties in measuring damage to privacy
24 interests, several states that provide a private right of action for privacy violations involving
25 genetic information also specify statutory damages, with higher amounts when the violation is
26 willful or leads to monetary gain for the violator. Alaska Stat. § 18.13.020 (actual damages plus
27 \$5,000, or plus \$1,000 if there is monetary gain); N.H. Rev. Stat. § 141-H:6 (not less than \$1,000
28 per violation); NM Stat. Ann. § 24-21-6 (economic loss plus damages of up to \$5,000 if the
29 violation results from willful or grossly negligent conduct). The Drafting Committee did not take
30 this approach because statutory damages often become a limit on the recovery available.

31
32 Several states also make civil penalties available to remedy unlawful discriminatory
33 practices. These penalties range from small (< \$1000) to significant amounts (up to \$50,000 or
34 \$100,000 per violation). Some states also authorize criminal penalties, although typically only
35 for willful violations of agency orders.

1 [ARTICLE] 3

2 LIFE INSURANCE, DISABILITY-INCOME INSURANCE,
3 AND LONG-TERM-CARE INSURANCE

4 SECTION 301. DEFINITIONS. In this [article]:

5 (1) “Adverse insurance determination” means a denial of coverage or the offering of less
6 favorable rates, terms, or conditions for insurance than would be available if the insurer did not
7 use genetic information in making the determination.

8 (2) “Disability-income insurance” means insurance intended to protect against loss of
9 occupational or professional earning capacity arising from injury, sickness, or disablement. The
10 term includes insurance that provides benefits for overhead expenses of a business, occupation,
11 or profession when the insured becomes disabled.

12 (3) “Family medical history” means information about a current or past medical condition
13 of a family member of an individual.

14 (4) “Family member” includes a person who is a dependant of an individual as the result
15 of marriage, birth, adoption, or placement for adoption and a person who is a first-degree,
16 second-degree, third-degree, or fourth degree relative of the individual or of the individual’s
17 dependant. The term includes deceased members of the family.

18 (5) “Genetic counseling” includes:

19 (A) assessing an individual’s genetic risk for an inherited condition by interpreting
20 family medical histories;

21 (B) providing nondirective education about the inheritance, testing, management,
22 and prevention of a genetic condition;

23 (C) helping an individual to understand the risks and benefits of testing for a

1 genetic trait to promote informed decision-making about whether or not to undergo genetic
2 testing;

3 (D) communicating and interpreting test results; and

4 (E) providing support, informational resources, and referrals as appropriate to help
5 an individual adapt to the medical, psychological, and familial implications of having or being at
6 risk of having a genetic condition.

7 (6) “Genetic education” means the process by which an individual acquires information
8 about the individual’s or the individual’s family member’s existing or suspected genetic
9 condition.

10 (7) “Genetic information” means:

11 (A) the results of a genetic test;

12 (B) information based on the genetic test of an individual or an individual’s family
13 member; or

14 (C) information that an individual or an individual’s family member requested or
15 received genetic services.

16 (8) “Genetic test” means an analysis of human genetic material, including
17 deoxyribonucleic acid, ribonucleic acid, chromosomes, proteins, and metabolites, that is intended
18 to detect:

19 (A) a genotype or genetic marker; or

20 (B) a mutation or chromosomal change.

21 (9) “Genetic service” means a genetic test, genetic counseling, or genetic education.

22 (10) “Insured” means an individual who is covered by or applying to be covered by life,
23 disability-income, or long-term-care insurance.

1 (11) “Insurer” means a person engaged in the business of life, disability-income, or long-
2 term-care insurance in this state, regardless of where a contract of insurance is entered into or
3 issued or a plan is administered. The term includes an insurance agent, broker, underwriter, and
4 third-party administrator.

5 (12) “Life insurance” means insurance against the financial risk of death.

6 (13) “Long-term-care insurance” means insurance that provides coverage for not less than
7 12 consecutive months for one or more necessary diagnostic, preventive, therapeutic,
8 rehabilitative, maintenance, or personal-care services provided in a setting other than an acute
9 care unit of a hospital. The term includes a policy or rider that provides for payment of benefits
10 based upon cognitive impairment or inability to perform the activities of daily living.

11 (14) “Person” means an individual, corporation, business trust, estate, trust, partnership,
12 limited liability company, association, joint venture, public corporation, government or
13 governmental subdivision, agency or instrumentality, or any other legal or commercial entity.

14 (15) “Predisposing genetic characteristic” means a gene variant or genetic marker that is
15 determined from genetic information and is associated with an individual’s increased risk of
16 developing a disease or medical condition for which the individual is presently asymptomatic.

17 (16) “Record” means information that is inscribed on a tangible medium or that is stored
18 in an electronic or other medium and is retrievable in perceivable form.

19 (17) “Sign” means, with present intent to authenticate or adopt a record:

20 (A) to execute or adopt a tangible symbol; or

21 (B) to attach to or logically associate with the record an electronic symbol, sound,
22 or process.

23 (18) “Tribunal” means a court, arbitral tribunal, or administrative agency.

1 **Reporter’s Notes**

2
3 *Paragraph (1). (Adverse insurance determination)* The use of genetic information makes
4 an insurance determination adverse if it leads to denial of coverage or coverage on less favorable
5 terms than would have been available absent the insurer’s consideration of the information. This
6 definition is relevant to an individual’s ability to correct a faulty genetic test that has
7 consequences for insurance eligibility or terms and conditions for issuance of insurance.
8

9 *Paragraph (2). (Disability-income insurance)* This definition of disability-income
10 insurance is used in several state statutes on genetic testing. *See, e.g.,* Cal. Ins. Code § 10147;
11 N.H. Rev. Stat. Ann. § 141-H:1. The Committee discussed substituting the term “income” for
12 “earning capacity,” but decided not to make this substitution.
13

14 *Paragraph (3). (Family medical history)* Family medical history is often a source of
15 genetic information in that it is used to evaluate the likelihood that an individual carries an
16 inherited trait. While the act’s employment article follows GINA and includes family medical
17 history within its definition of “genetic information,” the definition of “genetic information” in
18 the act’s insurance article does not encompass family medical history.
19

20 *Paragraph (4). (Family member)* The draft defines family member to encompass all
21 individuals whose genotype could influence an insurance decision. The term includes (1)
22 biological relations whose genetic information might provide information about the genetic
23 make-up of an individual employee or insured, (2) dependants whose risk of future genetically-
24 linked medical conditions could affect employer health care costs or family insurance coverage
25 and hence affect insurance decisions, and (3) those dependants’ biological relations whose
26 genetic information might provide information about the genetic make-up of a dependant.
27

28 *Degree of relationship to the individual or the individual’s dependents.* Genetic
29 counselors typically collect information on genetic diseases of family members related to the
30 third degree of consanguinity and often to the fourth degree, so this definition specifies the fourth
31 degree. The Drafting Committee considered a provision that would replace the designation
32 “fourth degree of consanguinity” with a list of family members, but decided instead to include
33 information in the notes that designates which family members are included within the fourth
34 degree of consanguinity. This information is included below.
35

36 Lineal consanguinity is the relationship between persons when one is directly descended
37 from the other. Each generation in this direct line constitutes a degree. Collateral consanguinity
38 refers to the relationship between persons who descend from the same common ancestor, but not
39 from each other. The civil law method of calculating degree of collateral consanguinity is to
40 count the number of generations from one person up to the common ancestor and then down to
41 the other person. This is the method reportedly used in many states. For consistency with the
42 employment article of this act, however, the following table is based on the proposed EEOC
43 regulations implementing GINA, which determine the degree of relationship by counting
44 generational levels separating individuals. The following table identifies the relatives within four
45 degrees of collateral consanguinity from an individual. Each row represents a generation and the
46 degree of consanguinity is given in parentheses.

1				Great-great-grandparents (4)
2			Great-grandparents (3)	
3		Grandparents (2)	Great Aunts and Great Uncles (3)	
4		Parents (1)	Aunts and Uncles (2)	
5	Individual	Sisters and Brothers and half-siblings (1)	First Cousins (3)	
6	Children (1)	Nieces and Nephews (2)	First Cousins once-removed (4)	
7	Grandchildren (2)	Grandnieces and Grandnephews (4)		
8				
9	Great-grandchildren (3)			
10				
11				
12	Great-great-grandchildren (4)			
13				
14				

15
16 *Paragraph (5). (Genetic counseling)* Genetic counseling is a key to an individual’s
17 informed decision making about getting a genetic test, understanding the result, and authorizing
18 its use, retention, or disclosure. Most states that license genetic counselors have a definition of
19 genetic counseling, but the majority of states do not license genetic counselors or regulate genetic
20 counseling. Note that the definition does not require that genetic counseling be performed by a
21 genetic counselor. Physicians and geneticists are also qualified to provide genetic counseling.
22

23 The definition uses the term genetic “condition,” which is intended to have a broad
24 interpretation. Genetic condition includes the concepts of genetic disease and disorder, but in
25 some circumstances it may also refer to a positive or benign trait or characteristic that is linked to
26 a particular genotype.
27

28 Genetic counseling is usually a two-step process consisting of 1) counseling before a test
29 about the decision whether or not to have the test and 2) counseling after the test if the test
30 indicates the individual is at risk. In addition, for some conditions counseling may also be
31 appropriate if the test indicates the individual is not at risk. The functions listed in (A)-(C) of the

1 definition of genetic counseling take place before an individual decides whether or not to have
2 the test. The functions in (D) and (E) take place after the test, if necessary.

3
4 *Paragraph (6). (Genetic education)* Genetic education is one element of genetic services.
5 It is typically less tailored to individual circumstances than a one-on-one genetic counseling
6 session. The definition is meant to be broad enough to include information provided by support
7 groups for genetic conditions to those who may have the condition. It is not meant to encompass
8 general genetic education such as that received in biology class or medical school.

9
10 *Paragraph (7). (Genetic information)* This definition of “genetic information” differs
11 from the definition in the employment article of the draft in that it excludes family medical
12 history. Even though family history is a major source of information to evaluate an individual’s
13 genetic risks, Article 3 does not change the practices of life, disability-income, and long-term-
14 care insurers, which traditionally have collected information on family history.

15
16 *Paragraph (8). (Genetic service)* “Genetic service” is a broader category than genetic
17 testing. The term includes activities associated with obtaining genetic information that could
18 create assumptions about an individual’s genetic status even in the absence of information about
19 genetic test results or medical history. “Counseling” implies a one-on-one consultation, so the
20 definition also includes “genetic education” in order to capture group information sessions on
21 genetic conditions. While the definition of a “genetic service” does not separately define the
22 term “genetic,” the term should be interpreted to be consistent with the definitions of “genetic
23 test” and “genetic information.”

24
25 This definition follows the definition of “genetic services” in the employment title of
26 GINA, except that the GINA definition expands on the term “genetic counseling” by noting
27 parenthetically that it “includ[es] obtaining, interpreting, or assessing genetic information.” The
28 draft has an independent, more comprehensive definition of genetic counseling and requirements
29 for employers and insurers to provide genetic counseling that exceed the protections of GINA.

30
31 *Paragraph (9). (Genetic test)* “Genetic test” is defined in terms of (1) the material that
32 the test analyzes and (2) the purpose of the test. This draft retains the definition used in the prior
33 draft. It now differs slightly from the definition in the employment article, which was changed to
34 follow the wording of GINA. The primary difference between the definitions is that the one used
35 in this article includes the concept of intent. It requires that the test be given with the intent to
36 detect a genotype, mutation, or chromosomal change. This requirement is included to help
37 assure insurance company representatives that the test will not be misused, as discussed below.

38
39 The first clause makes specific reference to the types of biological material that are
40 currently analyzed in genetic tests. Note that genetic tests can be conducted not only on gene
41 sequences, but also on biological products such as proteins or metabolites that can indicate
42 genetic make-up. The second clause specifies that the test must be for the purpose of
43 determining an individual’s genetic make-up, either through the identification of a genotype or
44 genetic marker or by looking for a mutation or chromosomal change.

45
46 Both clauses are equally important to the definition. First, some of the materials listed in

1 the first clause, especially proteins and metabolites, are tested for many medical purposes. A test
2 of a protein or metabolite does not constitute a genetic test unless it is administered for the
3 purpose of determining individual's genetic make-up as specified in the second clause.
4

5 Second, some genetic diagnoses are made without laboratory tests of the type listed in the
6 first clause. For example, a doctor may identify a genetic condition based on specific physical
7 features occurring in combination, or "dismorphology." This physical diagnosis of an
8 individual's genetic-make-up does not constitute a genetic test under the draft because it is not a
9 test of "genetic material."
10

11 Insurance industry representatives have expressed the fear that this definition is so broad
12 that it will sweep in routine medical tests such as blood tests of lipoproteins to measure
13 cholesterol levels. It is true that a cholesterol test analyzes proteins. A cholesterol test is not,
14 however, given specifically to detect a genotype, genetic marker, mutation, or chromosomal
15 change, so it would not be considered a genetic test under the draft. Instead, a high cholesterol
16 reading may indicate a number of causal factors, including inappropriate diet, lack of exercise,
17 and/or a condition called inherited familial high cholesterol. If the measurement of cholesterol
18 leads a doctor or insurance company to do further testing to see if an individual has a specific
19 genotype, then that would be a genetic test under the draft's definition. Other common medical
20 tests of proteins or metabolites that would not fall under the definition of "genetic test" include
21 urine tests for kidney disease, blood protein and creatinin tests for diabetes, blood tests of liver
22 enzyme proteins for liver function, urine tests measuring glucose to diagnose diabetes, blood
23 tests measuring serum blood glucose for diabetes, and triglycerides for heart disease.
24

25 The draft follows the example of states with definitions of genetic testing that are not
26 limited to identifying genotypes associated with diseases or impairments. (Fla, Haw, Mass, NH,
27 Ore, UT). In contrast, many other states statutes limit their definition of "genetic test" to testing
28 for disease-related genes. (Ariz, Ark, Del, Ill, Iowa, Kan, LA, Maine, MD, Mich, Minn, Nev,
29 MO, Neb, NJ, NM, NY, NC, OK, OR, RI, TX, VT, VA, WI). While most of the reasons that an
30 insurer might currently seek or use genetic information probably involve a disease, disorder, or
31 impairment, this may not always be the case. For example, an insurer could be interested in
32 reliable predictions of addictive behavior. While the current evidence linking behavior to genes
33 is tenuous, this area continues to be the subject of investigation.
34

35 *Paragraph (10). (Insured)* The definition of "insured" includes applicants. It
36 encompasses individuals with the types of insurance policies covered by the act.
37

38 *Paragraph (11). (Insurer)* The definition of "insurer" is intended to cover broadly
39 insurance companies and other persons and individuals that issue life, disability-income, or long-
40 term-care insurance and all persons who might obtain, use, or disclose genetic information
41 associated with that process. Nothing in this definition is intended to subject insurance agents,
42 brokers, underwriters, or third-party administrators to insurance regulations to which they are not
43 already subject.
44

45 *Paragraph (12). (Life insurance)* "Life insurance" is intended to be defined broadly.
46 This definition is drawn from N.H. Rev. Stat. § 401:1(III).

1 *Paragraph (13). (Long-term-care insurance)* The starting point for the definition of
2 “long-term-care insurance” is N.H. Rev. Stat. § 415-D:3(V). The definition is intended to
3 include all coverage of this nature whether it is provided on an expense-incurred, indemnity,
4 prepaid, or other basis.

5
6 *Paragraph (14). (Person)* This draft uses the broad version of the standard National
7 Conference of Commissioners on Uniform State Laws definition of “person.”

8
9 *Paragraph (15). (Predisposing genetic characteristic)* A “predisposing genetic
10 characteristic” refers to a genotype that signals an increased risk of a certain disease or condition.
11 The term does not include symptomatic diseases or conditions or genetic characteristics that are
12 manifest in a disease, medical condition, or disability. The broader terms “genetic test” and
13 “genetic information” may include both predisposing and manifest genetic characteristics as well
14 as genetic information that does not necessarily pertain to health.

15
16 While the terms “propensity” or “susceptibility” are often used, the actual manifestation
17 of a disease or condition may depend on a complex chain of events and the degree to which risk
18 is elevated may be quite small. The use of the term “predisposing” is meant to signal the tenuous
19 connection between a genotype or marker and a physical manifestation.

20
21 *Paragraph (16). (Record)* The definition of “record” is the standard National Conference
22 of Commissioners on Uniform State Laws definition.

23
24 *Paragraph (17). (Sign)* The definition of “sign” is the standard National Conference of
25 Commissioners on Uniform State Laws definition.

26
27 *Paragraph (18). (Tribunal)* The term “tribunal” refers collectively to the potential
28 decision-makers in a litigation or arbitration context.

29
30 **SECTION 302. GENETIC TESTING.**

31 (a) If an insurer files information on a genetic test that meets the standards of Section 306,
32 an insurer may request or require an insured to take the genetic test in connection with the
33 provision of life insurance, disability-income insurance, or long-term-care insurance and, with
34 prior authorization of the insured that meets the requirements of Section 303, may provide the
35 test to the insured.

36 (b) An insurer that requests or requires a genetic test in connection with the provision of
37 life insurance, disability-income insurance, or long-term-care insurance shall provide and pay for

1 genetic counseling for the insured about the risks and benefits of the genetic test before the
2 insured decides to authorize the test. The insured may knowingly and voluntarily waive
3 counseling in a signed record that informs the insured of the benefits of genetic counseling.

4 (c) An insurer that provides a genetic test to an insured in connection with the provision
5 of life insurance, disability-income insurance, or long-term-care insurance shall:

6 (1) pay for the genetic test;

7 (2) require the testing organization to make a report of the test result to the insured
8 and a health-care professional designated by the insured unless the insured directs otherwise;

9 (3) provide and pay for genetic counseling for the insured about a test result unless
10 the insured knowingly and voluntarily waives counseling in a signed record that informs the
11 insured of the benefits of genetic counseling; and

12 (4) require the destruction of the insured's biological sample obtained for a
13 genetic test as soon as permitted by law after the test is completed unless retention of the sample
14 is authorized by the insured, permitted by law other than this [act], or ordered by a tribunal.

15 **Reporter's Notes**

16
17 *Applicability of Article 3.* This article applies to life insurance, disability-income
18 insurance, and long-term-care insurance issued on an individual, group, or other basis. Including
19 individual policies is significant because individual insurance policies are subject to underwriting
20 and many life, disability-income, or long-term-care insurance policies are issued on an individual
21 basis. The draft does not distinguish between individual and group insurance, however, because
22 most of the states that regulate genetic testing or the use of genetic information for issuing life,
23 disability-income, or long-term-care insurance treat both individual and group insurance
24 identically.

25
26 GINA, ERISA, and HIPAA regulate acquisition, use, retention, and disclosure of genetic
27 information by health insurers. These statutes broadly preempt state regulation. There is,
28 however, no federal regulation or preemption of acquisition and use of genetic information by
29 life, disability-income, and long-term-care insurers. State regulation is important because life
30 insurance plays a central role in the financial lives of many individuals and families. Disability-
31 income and long-term-care insurance are increasingly viewed as a necessary adjunct to health
32 insurance and many states regulate disability-income and long-term-care insurance as health

1 insurance.

2
3 This draft treats life, disability-income, and long-term-care insurance identically in one
4 article. There are, however, differences in underwriting principles among the three types of
5 insurance. Life insurance underwriting is concerned with mortality and uses life expectancy
6 tables. In contrast, disability-income underwriting is concerned with morbidity and long-term-
7 care underwriting is a hybrid process.

8
9 *Genetic testing and genetic information.* This section and the section 304 limit
10 acquisition of genetic information by insurers that provide life, disability-income, or long-term-
11 care insurance. This section limits genetic testing and section 304 limits acquisition of genetic
12 information in general. The limitations are based on the philosophy that insurers may continue
13 current information gathering practices, but may not expand their collection of genetic
14 information unless and until there is a strong scientific basis for its use to predict mortality and
15 morbidity. It is the Drafting Committee's understanding that life, disability-income and long-
16 term-care insurers do not at present require applicants to take genetic tests, but do collect family
17 history information for use in determining eligibility and in underwriting.

18
19 The Drafting Committee considered, but did not adopt, an approach to regulating genetic
20 information for life, disability-income or long-term-care insurance based on the amount of the
21 insurance policy. The suggestion was to prohibit genetic testing and consideration of genetic
22 information for policies worth less than a specified monetary threshold. Above that value,
23 insurers would be permitted to consider genetic information freely.

24
25 The arguments for restricting acquisition of genetic information by the insurance industry
26 are that this information is particularly private and its predictive power is easily exaggerated.
27 There are privacy concerns with commercial acquisition of sensitive genetic information and
28 predictions that individuals will avoid genetic testing for fear of adverse effects on their
29 insurability. There is also a possibility that insurers may require applicants to take genetic tests
30 and then deny insurance or charge more based on genetic characteristics, unfairly making
31 coverage unavailable to people who are not sick from the genetic condition and never will
32 become sick from that condition. From the industry perspective, as with health insurance,
33 insurers worry about adverse selection. If applicants seek coverage because a genetic
34 characteristic exposes them to risk, but the insurer does not have this information, this puts the
35 insurer at a financial disadvantage. *See generally* Mark A. Rothstein, ed., *Genetics and Life*
36 *Insurance: Medical Underwriting and Social Policy* (2004).

37
38 A 1997 study by the Human Genetics Advisory Commission in the United Kingdom
39 concluded that it is unlikely that actuarially-sound genetic predictions of adult death will be
40 validated and available anytime in the near future. Genetic tests need to be connected to medical
41 and epidemiological research to establish what consequences for health and life-span can be
42 inferred from a given genetic test. The Commission concluded that a requirement to disclose
43 genetic tests as a condition of obtaining insurance would be acceptable only after research has
44 established an association between a given pattern of test results and life events that are relevant
45 for the insurance product. It recommended continuing a moratorium on requiring test results.
46 Human Genetics Advisory Commission, *The Implications of Genetic Testing for Insurance*

1 (1997).

2
3 *Genetic testing.* This section prohibits insurers from requiring applicants to have genetic
4 testing as a condition of obtaining life, disability-income or long-term-care insurance unless
5 scientific developments support a conclusion that a test provides a relevant prediction. The
6 section is consistent with genetic testing prohibitions in force in California, Massachusetts, and
7 Vermont, except that it allows the prohibition to be modified as justified by scientific
8 developments. Vermont and Massachusetts prohibit insurers from requiring applicants to take a
9 genetic test as a condition of obtaining or renewing a policy. California prohibits long-term-care
10 insurers from requiring genetic testing for use in determining insurability or in underwriting. *See*
11 Cal. Ins. Code § 10233.1 (long-term-care insurance); Mass. Gen. L. Ann. 175 § 120E (life
12 insurance); Mass. Gen. L. Ann. 175 § 108I (disability and long-term-care insurance); Vt. Stat.
13 Ann. § 9334 (any insurance).

14
15 The section also sets forth requirements similar to those imposed on employers who
16 provide genetic tests.

17
18 *Genetic Counseling.* This section requires insurers who have applicants take genetic tests
19 to provide genetic counseling. The counseling occurs in two stages: before the test to assist in
20 the decision to take the genetic test and after the test to interpret results if the test indicates the
21 individual is at risk. Counseling is an important component of the testing process in the field of
22 genetics for several reasons. Tests may indicate a risk of a condition for which there is no
23 treatment and the information may have implications for family members who are not tested
24 directly. The outcomes require interpretation of complex probabilities which can be easily
25 misunderstood. The genetic counseling that is required before the test is covered in subsection
26 (b) and the counseling that is appropriate after a test is covered in subsection (c).

27
28 The Committee received differing opinions from industry participants on this issue which
29 ranged from opposition to any obligation to provide counseling to a view that if insurance
30 companies request the tests they should provide and pay for counseling in conjunction with the
31 test.

32
33 **SECTION 303. AUTHORIZATION FOR GENETIC TEST.**

34 (a) An insured's authorization for the genetic test requested or required under Section 302
35 must be knowing and voluntary and indicated in a record signed by the insured that complies
36 with subsection (b) of this section. An insurer that receives a valid authorization for genetic
37 testing may provide a test only in accordance with the authorization. An authorization may not
38 expand the genetic testing permitted by this [act] and may not include exculpatory language
39 waiving any of the insured's legal rights.

1 (b) An authorization for a genetic test for life insurance, disability-income insurance, or
2 long-term-care insurance must:

3 (1) describe the genetic test to be performed, its purpose, and its permitted uses;

4 (2) state that only the authorized genetic test will be performed on the insured's
5 biological sample;

6 (3) inform the insured that the insurer is obligated to provide and pay for genetic
7 counseling about the risks and benefits of the test before the insured decides to authorize the test;

8 (4) inform the insured that the insurer is obligated to provide and pay for genetic
9 counseling about the test result unless the insured waives genetic counseling;

10 (5) state that the test result will be reported to the insured and a health-care
11 professional designated by the insured, unless the insured directs otherwise;

12 (6) include an opportunity for the insured to provide directions about reporting
13 test results;

14 (7) inform the insured that the insured's biological sample will be destroyed as
15 soon as permitted by law after the test is completed unless the insured authorizes retention of the
16 sample or unless otherwise ordered by a tribunal; and

17 (8) state that the insured is entitled to a copy of the authorization.

18 (c) The use of the following form complies with this section.

19 Authorization for Genetic Testing

20 Limited Authorization. Only the genetic tests that you authorize on this form will be performed
21 on your biological sample. These tests are voluntary, but refusing a test requested by
22

23 _____ may mean that your application for insurance will be denied.
24 [name of insurer]
25
26
27
28

1 Availability of Genetic Counseling. Before you complete this authorization, it is highly
2
3 recommended that you meet with a genetic counselor who will help you understand and evaluate
4
5 the risks, benefits, and consequences for you and your family of having the tests listed below.

6
7 _____ will provide and pay for this genetic counseling.
8 [Name of insurer]

9
10
11 Proposed Genetic Tests. Based on a review of your family medical history, _____
12 [name of insurer]
13 requests the following genetic test:

14
15
16 _____
17 [Name of test]

18
19 The purpose of this test is to determine if you have a predisposition for _____ .
20 [genetic condition]

21 If you authorize _____ to have access to the test result, it will be used only for the
22 [insurer]
23 following purposes: _____.

24
25
26 Reporting Test Results and Genetic Counseling. The test results will be reported to you and to a
27
28 health-care professional whom you designate unless you direct otherwise. It is recommended that
29
30 you receive genetic counseling about the test results. Genetic counseling is important for
31
32 understanding the test results in the context of your medical and family history. It can also
33
34 provide you with support, informational resources, and referrals, as appropriate, that can help you
35
36 adapt to the implications of being at risk of a genetic condition. _____

37 [Name of insurer]
38 will provide and pay for genetic counseling about the test results unless you decline genetic
39
40 counseling.

41
42
43 Destruction of your Biological Sample. After the genetic test, your biological sample will be
44
45 destroyed as soon as permitted by law unless or a court, arbitral tribunal, or administrative
46

1 agency requires retention of the sample or you sign a written authorization for _____
2 [name of insurer]
3 to keep the sample.

4
5 Retention of Legal Rights. By signing this authorization, you do not lose any legal rights to
6
7 which you are entitled.

8
9 Copy of this form. You are entitled to a copy of this authorization.

10
11
12 I, _____, authorize the genetic test(s) I have checked above.
13 [print name]

14
15 I wish to receive test results.

16 I do not wish to receive test results.

17
18 Report test results to the following health care professional:

19 Name: _____

20 Address: _____

21
22 Do not report test results to a health care professional.

23
24
25 _____
Signature

_____ Date

26 27 **Reporter's Notes**

28
29 This section sets forth an authorization requirement for genetic testing and the elements
30 that must be contained in an authorization form. The term "authorization" is used instead of
31 "informed consent" to avoid confusion with the use of that term in medical practice.

32
33 The Drafting Committee decided that the best method to protect privacy for genetic
34 testing and genetic information is to establish an authorization requirement that is coupled with
35 statutory limits and duties imposed on insurers. Under this approach, an insured must
36 affirmatively authorize any genetic testing or acquisition, use, retention, or disclosure of genetic
37 information. The authorization requirement is not simply a procedural step because Article 3
38 establishes limitations on the situations in which insurers may request authorization from
39 insureds.

40
41 The Drafting Committee considered, but did not adopt alternatives that would (1)
42 establish a general property right in a biological sample an individual provides for genetic testing
43 and in the resulting genetic information or (2) establish a limited property applicable only to the
44 context of insurance.

45
46 *Subsection (a) Requirement for authorization for genetic testing.* Under Section 302, an

1 insurer may require a genetic test as a condition of obtaining life, disability-income, or long-
2 term-care insurance if the test has been filed and meets the standards of Section 306. This
3 subsection adds an additional requirement that genetic testing is permitted only with the prior
4 authorization of the insured.
5

6 In order to meet the requirement that an authorization be knowing and voluntary, an
7 employee or insured should have genetic counseling before signing the authorization. Genetic
8 counseling provides insureds with adequate information to make an informed decision about
9 genetic testing. It also makes them aware of their options regarding reporting of test results and
10 help in interpreting them through genetic counseling. Genetic counseling may be provided by a
11 genetic counselor, but may also be provided by a qualified physician or geneticist.
12

13 Other law of the state may provide for a substitute decisionmaker or signer if the
14 employee is incapacitated or incompetent. This situation is left to existing law of the state that
15 governs power of attorney, guardianship, or other substitute decision makers.
16

17 *Subsection (b) Content of authorization for testing.* The section draws on N.Y. Civ.
18 Rights Law § 79-1 (McKinney), which establishes requirements for consent for a genetic test.
19

20 The limitation in (b)(2) to the authorized test is consistent with the requirements for prior
21 authorization in Section 302.
22

23 The notification provision regarding destruction of the sample in subsection (b)(7) is
24 consistent with the insurer's obligation to ensure the sample is destroyed under Section
25 302(c)(4), which recognizes that the testing laboratory may be required to retain the sample for
26 certification purposes.
27

28 *Subsection (c). Authorization form.* The subsection provides a form that may be used to
29 authorize an insurance company to provide a genetic test. The use of a form following this
30 pattern would comply with the requirements of the section.
31

32 **SECTION 304. ACQUISITION OF GENETIC INFORMATION.**

33 (a) Unless an insurer has filed information on a genetic test that meets the standards of
34 Section 306, an insurer may not knowingly obtain or directly or indirectly inquire about, request,
35 or require an insured to provide the insured's genetic information based on a genetic test in
36 connection with the provision of life insurance, disability-income insurance, or long-term-care
37 insurance.

38 (b) Nothing in this [article] prohibits an insurer from obtaining medical records of an

1 applicant for insurance that contain genetic information in connection with the provision of life
2 insurance, disability-income insurance, or long-term-care insurance.

3 (c) An insurer may request or require an insured to provide family medical history in
4 connection with the provision of life insurance, disability-income insurance, or long-term-care
5 insurance.

6 **Reporter's Notes**
7

8 This section limits the extent to which an insurance company may acquire genetic
9 information or the results of genetic testing based on the rationale discussed in the reporter's
10 notes to Section 302. Subsection (a) permits acquisition of genetic information if it is based on a
11 genetic test that meets the standards set forth in Section 306.
12

13 Subsection (b) is included to reassure the industry that its traditional access to medical
14 records is preserved, despite the fact that medical records may contain genetic information.
15

16 The prohibition on acquisition of genetic information does not apply to family medical
17 history, which is not included in the definition of "genetic information." Subsection (c),
18 moreover, explicitly permits insurers to seek information about family medical history, which
19 they have traditionally used for underwriting.
20

21 **SECTION 305. PROHIBITION ON USE OF GENETIC INFORMATION.** Unless
22 genetic information is based on a genetic test that has been filed and meets the standards
23 provided in Section 306, an insurer may not use the genetic information about an insured's
24 predisposing genetic characteristics to determine eligibility for or rates, terms, and conditions of
25 life insurance, disability-income insurance, or long-term-care insurance.

26 **Reporter's Notes**
27

28 The determination of eligibility for coverage includes decisions made in connection with
29 the offer, sale, continuation, or renewal of an insurance policy. The determination of rates,
30 terms, and conditions includes establishing premiums, limiting coverage, limiting or conditioning
31 benefits, or making any other underwriting decisions.
32

33 This section prohibits the use of genetic information for determining eligibility or
34 underwriting of life, disability-income, and long-term-care insurance unless the genetic test has
35 been filed and meets that standards provided in Section 306. Traditional insurance underwriting

1 has been based on medical histories and tests that indicate existing medical conditions. The draft
2 permits those practices to continue. Using predictions based on predisposing genetic
3 characteristics that have not been expressed as a disease or condition would be a new step,
4 however, and there is a great risk that such predictions would not be reliable in the context of
5 insurance.

6
7 The restriction on use of genetic information in life, disability-income & long-term-care
8 insurance applies only to predisposing genetic characteristics. Therefore, insurers are not
9 restricted from using genetic information with regard to a medical condition that has been
10 diagnosed as manifest in an individual.

11
12 The section ties use of genetic information about predisposing characteristics to the
13 process in Section 306 for ensuring that the genetic test provides a reliable prediction of
14 individual mortality or morbidity. If an insurer has filed information to show that a genetic test is
15 valid, it may use the results of that test in underwriting. Otherwise, life, disability-income and
16 long-term-care insurers may not use genetic information about predisposing characteristics for
17 determining eligibility or in underwriting.

18
19 This prohibition is consistent with regulation in a number of states. Because genetic tests
20 are not yet routine in medical care and few individuals have previously taken genetic tests when
21 they apply for insurance, the prohibitions on requiring tests in California, Massachusetts, and
22 Vermont have the effect of preventing the use of genetic information in insurance
23 determinations. In addition, a number of states directly prohibit insurers from using genetic
24 information to determine eligibility or in underwriting. *See* Colo. Rev. Stat. § 10-3-1104.7(3)(b)
25 (group disability-income & long-term-care); Kan. Stat. Ann. § 40-2259(d) (disability-income &
26 long-term-care); Or. Rev. Stat. § 746.135 (genetic information from a blood relative for life,
27 disability-income & long-term-care insurance); Vt. Stat. Ann. tit. 18, § 9334(a) (same). *See also*
28 Ariz. Rev. Stat. Ann. § 20-448(F) (permitting disability-income and long-term-care insurers to
29 use genetic information only if there is an actual diagnosis of a genetic condition).

30
31 The insurance industry maintains that any restrictions on their ability to use genetic
32 information will undermine the availability and pricing structure of life, disability-income &
33 long-term-care insurance. However, there is broad international consensus that the use of genetic
34 information in life insurance should be restricted. Numerous countries have enacted restrictions,
35 as have the states noted above. There is no evidence, moreover, that these restrictions have been
36 associated with adverse selection, increased pricing, reduced availability of policies, or decreased
37 profitability of the insurance industry. Without some supporting evidence, these industry
38 concerns do not outweigh the importance of protecting against new uses of information that
39 would diminish privacy and that carry a high risk of irrational discrimination.

40
41 With the draft's narrow definition of "genetic information," an insurer would be able to
42 use genetic data revealed by an individual's family medical history to determine eligibility or to
43 underwrite without restriction. One member of the Committee raised the question of whether
44 there should be any limits on insurers' use of family medical history. The question was
45 motivated by a concern that even if disclosures to insurers do not change, insurers may be able to
46 do more with those disclosures using ever more sophisticated computer technology. The

1 Drafting Committee did not consider if it would be desirable to prevent new uses of family
2 history information or what limits would be appropriate.
3

4 **SECTION 306. REQUIRED DETERMINATION AND FILING FOR GENETIC**
5 **TESTING AND ACQUISITION AND USE OF GENETIC INFORMATION.** A life
6 insurer, disability-income insurer, or long-term-care insurer may request or require a genetic test
7 or acquire and use genetic information based on the results of a genetic test if the insurer files
8 with the [state commissioner of insurance] the test and documentation supporting to a reasonable
9 degree of scientific certainty the test’s analytical validity, clinical validity, and a scientific
10 association between the test and an increased risk of morbidity or mortality. The insurer’s use of
11 genetic information about an insured’s predisposing genetic characteristic to determine eligibility
12 or rates, terms, or conditions for life insurance, disability-income insurance, or long-term-care
13 insurance without a filing by the insurer that meets this standard is a violation of the [state unfair
14 practices insurance law].

15 ***Legislative Note:*** [State unfair practices insurance law] should be replaced with the title of the
16 relevant statute and [state commissioner of insurance] should be replaced with the appropriate
17 title.
18

19 **Reporter’s Notes**
20

21 The risk of misuse of genetic information is increasing because of the explosion of
22 genetic tests available, the general lack of governmental oversight for these tests, and common
23 misperceptions about the extent to which a genetic test can predict a future medical disease or
24 condition. In addition, the pathways for gene expression remain uncertain. Links between most
25 genetic characteristics and the incidence of disease are extremely complex and depend on the
26 interrelation of many factors, both genetic and environmental.
27

28 Even with draft’s restrictions on genetic testing by insurance companies, access to genetic
29 information in medical records will increase. More than 1,000 genetic tests are available
30 clinically as of early 2007; hundreds more are available to researchers. Some are marketed
31 directly to consumers with claims that they can be used to individually customize vitamins and
32 diet as well as test for future disease. There is no government oversight of the validity of the
33 tests used for research or available through medical professionals. Through the mechanisms of
34 this section that protect against the premature or improper use of predictions based on genetic

1 information, the draft provides assurance that insurance companies are permitted to use genetic
2 information, but not misuse it.

3
4 The insurance industry has expressed a view that it must be able to develop its use of
5 genetic information along with the rapid development of knowledge in the genetic field. The
6 section provides a mechanism that will allow use of genetic information to evolve, in response to
7 new scientific information that may justify the use of genetic information for eligibility and
8 underwriting determinations as determined by an evidence-based review process.

9
10 The Drafting Committee considered and rejected an approach that would have established
11 regulatory oversight of the use of genetic information by insurers by requiring a prior finding of
12 an association with mortality or morbidity by state insurance regulators in consultation with state
13 public health authorities. The Committee also considered and rejected an approach that would
14 have required that the appropriate finding be made by a geneticist or genetic counselor. Instead,
15 the Drafting Committee decided that the insurance industry should be responsible for
16 determining the accuracy and completeness of the data on a genetic test and the reliability of the
17 prediction possible with the genetic information.

18
19 The approach selected by the Committee requires an insurance company to identify
20 genetic tests that it plans to use and to file documentation supporting the validity of the test with
21 the state insurance commissioner. This documentation would then be open to public scrutiny,
22 creating transparency that can provide a check on a company's determination. This process will
23 allow an insurer's use of genetic information to change as research develops reliable connections
24 between genetic characteristics and risk of mortality or morbidity.

25
26 The process required here contemplates the type of evidence-based review of genetic tests
27 conducted by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP)
28 Working Group formed under the auspices of the Centers for Disease Control National Office of
29 Public Health Genomics. See <http://www.cdc.gov/genomics/gtesting/EGAPP/about.htm>.

30
31 As explained in the following excerpt from the Final Report of the Task Force on Genetic
32 Testing, Promoting Safe and Effective Genetic Testing in the United States (1997) (available at
33 <http://www.genome.gov/10001733>), before relying on a genetic test, there must be scientific
34 evidence to (1) establish a reliable relationship between a disease, genes, and inherited mutations;
35 (2) establish the analytical validity of the test; and (3) establish the clinical validity of the test.

36 37 Establishing Associations Between a Disease, Genes, and Inherited Mutations

38
39 In developing genetic tests, scientists must first be confident that the DNA
40 segments under investigation play a role in the disease in question. These
41 segments might be apparently functionless markers that appear to be spatially
42 linked on a chromosome to a disease-related gene. Linkage is demonstrated
43 when, within families, one form of the marker is found in those with the disease
44 more often than in blood relatives in whom the disease is absent. Because such
45 associations might be due to chance, as was the case for the linkage claimed
46 between bipolar affective disorder and markers on chromosome 11, and between

1 schizophrenia and markers on chromosome 5, stringent statistical standards must
2 be satisfied before accepting linkage, and the findings must be confirmed in
3 additional families with the disease. . . .

4
5 Further research leads scientists from the linked, functionless marker to a nearby
6 gene suspected of being causally related to the diseases in question. The proof
7 depends on finding mutations in the gene that are only present (in gene dosage
8 sufficient to cause disease) in family members with disease. Further proof that a
9 gene is causally related to disease comes from demonstrating that the protein
10 encoded by the gene is absent, not synthesized in adequate amounts, or manifests
11 a structural or functional aberration that plausibly accounts for symptoms and
12 signs of the disease.

13
14 Another approach to identifying a disease-related gene does not depend on linkage
15 but on suspecting that a gene that has been previously identified (“candidate
16 gene”) plays a role in a specific disease. Here too, mutations must be found only
17 in those with the disease.

18
19 The DNA segments associated with a disease might be functional, common,
20 polymorphic gene variants. Recently, attention has been given to the association
21 between the apolipoprotein E polymorphism and Alzheimer disease (AD). A
22 higher proportion of people with apoE4 will develop AD than those with other
23 forms of the polymorphism. Some people with AD, however, will not inherit
24 apoE4 and other with apoE4 will never develop AD; the polymorphism is neither
25 a necessary nor sufficient cause for the disease. It is not clear whether
26 polymorphic variants themselves predispose to the disease, whether the
27 association is spurious (unlikely in the case of apoE4 and AD), or whether a
28 marker linked to both the polymorphic gene and the disease-related gene is
29 responsible. The following criterion must be satisfied before either linked
30 markers or putative disease-related mutations are used as the basis of a genetic
31 test. **The genotypes to be detected by a genetic test must be shown by**
32 **scientifically valid methods to be associated with the occurrence of a disease.**
33 **The observations must be independently replicated and subject to peer**
34 **review.**

35 36 Analytical Validity

37
38 For DNA-based tests, analytical validity requires establishing the probability that
39 a test will be positive when a particular sequence (analyte) is present (analytical
40 sensitivity) and the probability that the test will be negative when the sequence is
41 absent (analytical specificity). In contrast to DNA-based tests, enzyme and
42 metabolite assays measure continuous variables (enzyme activity or metabolic
43 concentration). One key measure of their analytical validity is accuracy, or the
44 probability that the measured value will be within a predefined range of the true
45 activity or concentration. Another measure of analytical validity is reliability, or
46 the probability of repeatedly getting the same result.

1 [V]alidation includes performing replicate determinations to ensure that a single
2 observation is not spurious, and “blind” testing of coded positive samples (from
3 patients with the disease in whom the alteration is known to be present) and
4 negative samples (from controls). Organizations engaged in new test
5 development should have access to a sufficient number of patient samples to have
6 statistical confidence in the validation. In validating a new test analytically, the
7 laboratory techniques should be as similar as possible to those used when the test
8 will be performed clinically once it is validated.
9

10 **Analytical sensitivity and specificity of a genetic test must be determined**
11 **before it is made available in clinical practice.**

12
13 **Clinical Validity**
14

15 Clinical validity involves establishing several measures of clinical performance
16 including (1) the probability that the test will be positive in people with the
17 disease (clinical sensitivity), (2) the probability that the test will be negative in
18 people without the disease (clinical specificity), and (3) the probability that people
19 with positive test results will get the disease (positive predictive value (PPV)) and
20 that people with negative results will not get the disease (negative predictive
21 value.) Predictive value depends on the prevalence of the disease in the group or
22 populations being studied, as well as on the clinical sensitivity and specificity of
23 the test.
24

25 Two intrinsic features of genetic diseases, heterogeneity and penetrance, affect
26 clinical validity.
27

28 *Heterogeneity.* The same genetic disease might result from the presence (in the
29 necessary gene dosage) of any of several different variants (alleles) of the same
30 gene (allelic diversity) or of different genes (locus heterogeneity). With current
31 technology, all disease-related alleles cannot always be identified, particularly
32 when there are many of them, which is often the case. This failure to detect all
33 disease-related mutations reduces a test’s clinical sensitivity.
34

35 *Penetrance.* The probability that disease will appear when a disease-related
36 genotype is present is the penetrance of the genotype. When penetrance is
37 incomplete, PPV is reduced. Penetrance is incomplete when other genetic or
38 environmental factors must be present. In high-risk breast cancer families, 10 to
39 15 percent of women with inherited susceptibility mutations of the BRCA1 gene
40 will never develop breast cancer. Environmental factors and possibly other
41 inherited factors are required as well. In women without a family history of breast
42 cancer, the penetrance of a BRCA1 or BRCA2 is even lower. Alleles at other
43 gene loci and similar environments are more likely to be shared by relatives than
44 by people in the general population.
45

46 * * *

1 Parameters of clinical validity will depend in part on the group r population in
2 which the test will be used. For instance, the frequency of disease-related alleles
3 might differ between ethnic groups, making it difficult if not impossible to
4 extrapolate the test sensitivity from one group to another. This is the case for
5 cystic fibrosis and breast cancer in which certain alleles can predominate in one
6 ethnic group or geographical area but not in others. Penetrance can also differ
7 among ethnic groups. The prevalence of allele frequencies will have a marked
8 effect on PPV; the greater the prevalence, the higher the PPV. Age will also
9 affect allele prevalence; in a population older than the age at which the disease
10 usually causes death, the allele frequency will be lower than in a younger
11 population. For all these reasons, validation studies should be conducted in a
12 group representative of the one in which the test is intended for clinical use.

13
14 When tests are developed for one purpose are used for another, there is no
15 assurance that the sensitivity or PPV will be the same. . . .

16
17 The three following criteria help ensure that appropriate data on the clinical
18 validity of genetic tests will be collected during the developmental stages.

- 19
20 • **Data to establish the clinical validity of genetic tests (clinical**
- 21 **sensitivity, specificity, and predictive value) must be collected under**
- 22 **investigative protocols.**
- 23 • **In clinical validation, the study sample must be drawn from a group**
- 24 **of subjects representative of the population for whom the test is**
- 25 **intended.**
- 26 • **Formal validation for each intended use of a genetic test is needed.**
- 27

28 (emphasis in original, citations omitted)

29
30 **SECTION 307. CORRECTION OPTION FOR GENETIC INFORMATION.** If an
31 insurer uses an insured's genetic information to make an adverse determination regarding
32 eligibility or rates, terms, or conditions for life insurance, disability-income insurance, or long-
33 term-care insurance, the insurer shall provide notice of that use to the insured. The insured may
34 choose to repeat a genetic test to verify the analysis used in the adverse determination. If the
35 initial test was performed at the request of the insurer, the insurer shall pay for a repeat test
36 requested by the insured. If the first analysis is found to be inaccurate, the insurer shall
37 reconsider the adverse determination.

1 **Reporter's Notes**

2
3 Under this section, an insured is provided an opportunity to correct mistakes in genetic
4 information. The section is modeled on Florida procedures which require the DNA analysis to
5 be repeated in the event of an adverse determination. Fla. Stat. § 760.40(3). Delaware also has a
6 special provision that allows an individual to access his genetic records and to correct those
7 records. 16 Del. Code Ann. § 1223.
8

9 **SECTION 308. CONFIDENTIALITY; RETENTION OF GENETIC**

10 **INFORMATION.** An insured's genetic information is a confidential medical record. Except as
11 otherwise provided by law other than this [act], a life insurer, disability-income insurer, or long-
12 term-care insurer may keep an insured's genetic information only with authorization of the
13 insured in accordance with Section 310.

14 **Reporter's Notes**

15
16 This section permits insurers to retain genetic information under certain circumstances. It
17 follows the practice of the states with statutes that require authorization or informed consent for
18 the retention of genetic information and do not treat life, disability-income, or long-term-care
19 insurers differently than others who might retain such information. It departs from the approach
20 of some other states, however, that exempt these insurers from their requirements for
21 authorization or informed consent. (E.g., Mass., Nev., NH, NMex, Ok)
22

23 There are arguments that insurers should not be limited in retaining genetic information.
24 They typically have two years to rescind a policy for misrepresentation, and may need the
25 information submitted with the application in order to show misrepresentation. In addition,
26 reinsurers may audit underwriting practices several years after a policy issues. Insurance industry
27 representatives state that under current practice, information is retained indefinitely because of
28 the risk of class action suits.
29

30 **SECTION 309. DISCLOSURE OF GENETIC INFORMATION.**

31 (a) Except as otherwise provided in Section 310, a life insurer, disability-income insurer,
32 or long-term-care insurer may disclose an insured's genetic information to a person other than the
33 insured only if the insurer has obtained the insured's prior authorization for the disclosure in
34 accordance with Section 310.

1 (b) An insured, upon request, may inspect and obtain a copy of genetic information from
2 the insurer's files on the insured.

3 **Reporter's Notes**

4
5 *Subsection (a).* This subsection restricts the ability of life, disability-income, and long-
6 term-care insurers to disclose genetic information without authorization of the insured.

7
8 The insurance industry argues that disclosures are necessary for business purposes and
9 that a special disclosure provision for genetic information is unnecessary because a number of
10 states have adopted statutes based on National Association of Insurance Commissioners' model
11 laws dealing with general privacy of information. In the Drafting Committee's view, disclosures
12 of genetic information are not protected adequately when there are broad exceptions that allow
13 this information to be shared for business purposes.

14
15 *Subsection (b).* Under this subsection, an insured is allowed to access an insurer's
16 records of his genetic information. In combination with the procedure in Section 307, this
17 enables an insured to correct those records.

18 19 **SECTION 310. AUTHORIZATION FOR ACQUISITION, USE, RETENTION,** 20 **OR DISCLOSURE OF GENETIC INFORMATION.**

21 (a) Except as otherwise provided by this [act] or law other than this [act], an insurer may
22 not acquire, use, keep, or disclose an insured's genetic information without the insured's
23 knowing and voluntary authorization indicated by a record signed by the insured that complies
24 with subsection (c) of this section. An insurer that receives a valid authorization may acquire,
25 use, keep, or disclose genetic information only in accordance with the authorization. An
26 authorization shall not expand the acquisition, use, retention, or disclosure of genetic information
27 permitted by this [article] and may not include exculpatory language waiving any of the insured's
28 legal rights.

29 (b) Except as otherwise provided by this [act] or law other than this [act], a person who
30 receives genetic information disclosed by an insurer must maintain the confidentiality of the
31 insured's genetic information and may not disclose the information without the insured's

1 knowing and voluntary authorization indicated by a record signed by the insured that complies
2 with subsection (c) of this section. A recipient that receives the insured's valid authorization to
3 disclose genetic information may disclose the information only in accordance with the
4 authorization. An authorization may not expand the disclosure of genetic information permitted
5 by this [article] and may not include exculpatory language waiving any of the insured's legal
6 rights. When an insurer discloses an insured's genetic information, it must notify the recipient of
7 the information about these obligations.

8 (c) An authorization to acquire, use, keep, or disclose an insured's genetic information
9 must:

10 (1) describe the genetic information to be acquired, used, kept, or disclosed in a
11 specific and meaningful fashion;

12 (2) identify or describe the person that is authorized to acquire, use, keep, or
13 disclose the genetic information;

14 (3) if the authorization is for acquisition of genetic information through disclosure
15 by another person to an insurer, identify or describe the person authorized to make the disclosure;

16 (4) if the authorization is for use of genetic information, describe the permitted
17 uses;

18 (5) if the authorization is for retention of genetic information, describe where the
19 information will be kept and identify or describe the custodian of the information;

20 (6) if the authorization is for disclosure to a third person, identify or describe the
21 third person to which the authorized person may disclose the genetic information;

22 (7) indicate the duration of the authorization with an expiration date if any or
23 expiration event that relates to the insured or to the purpose of the acquisition, use, retention, or

1 disclosure;

2 (8) state that the insured may revoke the authorization at any time in a signed
3 record, subject to the right of an insurer or other person that acted in reliance on the authorization
4 before receiving notice of revocation, and provide instructions on how to revoke an
5 authorization; and

6 (9) state that the insured is entitled to a copy of the authorization.

7 (d) The use of the following forms complies with this section.

8 Authorization for Acquisition and Use of Genetic Information

9
10 _____ requests your authorization to acquire the following genetic test results
11 and

12 [Name of insurer]
13 use them for the purposes identified:

14
15
16 Access to the results of the test for _____. The purpose
17 [name of test and condition tested for]
18 of this test is to determine if you have a genetic characteristic that predisposes you towards the
19 following medical condition: _____. _____ will use this information
20 [Name of insurer]
21 only for the following purposes: _____.

22
23
24
25 Disclosure by _____ of genetic information about _____
26 [name of person to disclose] [name of test
27 _____ to _____. _____ will use this information
28 and condition] [name of insurer] [Name of insurer]
29 only for the following purposes: _____.

30
31
32 You may revoke this authorization for acquisition and use at any time by sending a letter to

33
34 _____ unless _____ has _____
35 [name and address] [name of insurer] [description of action that would
36 _____
37 be taken based on the information]

1 You are entitled to a copy of this authorization. By signing this authorization, you do not lose
2
3 any legal rights to which you are entitled. This authorization is valid until _____.
4 [date or event]
5
6
7

8 I, _____, authorize _____ to acquire and use my genetic
9 [print name] [name of insurer]
10 information as checked above.
11
12

13 _____
14 Signature Date

15
16
17 Authorization for Retention of Genetic Information

18
19 _____ requests your authorization to keep the following genetic information:
20 [Name of insurer]
21

22
23 _____
24 [Name of test and condition tested for]
25

26
27 You may revoke this authorization for _____ to keep your genetic information at
28 [name of insurer]
29 any time by sending a letter to _____ unless _____
30 [name and address] [name of insurer]
31 has _____.
32 [description of action that would be taken based on the information]
33
34

35 You are entitled to a copy of this authorization. By signing this authorization, you do not lose
36
37 any legal rights to which you are entitled. This authorization is valid until _____.
38 [date or event]
39
40

41 I, _____, authorize _____ to keep the genetic information
42 [print name] [name of insurer]
43 checked above.
44

45 _____
46 Signature Date

1 Authorization for Disclosure of Genetic Information

2
3 _____ seeks your authorization to disclose the following genetic information to
4 [Name of insurer]
5 _____ will notify _____
6 [name of recipient of the information] [Name of insurer] [name of recipient]
7
8 _____ that _____ is legally obligated
9 [name of recipient of the information] [name of recipient of the information]
10 to maintain the confidentiality of this information and that if may not make further disclosures
11
12 without your authorization.

13
14
15 _____
16 [Name of test and condition tested for]
17

18
19 You may revoke this authorization for disclosure at any time by sending a letter to
20 _____ unless _____ has already disclosed the information.
21 [name and address] [name of insurer]
22
23

24
25 You are entitled to a copy of this authorization. By signing this authorization, you do not lose
26
27 any legal rights to which you are entitled. This authorization is valid until _____.
28 [date or event]
29

30
31 I, _____, authorize _____ to
32 [print name] [name of person authorized to make disclosure]
33 disclose my genetic information checked above to _____.
34 [name of recipient of the information]
35

36
37 _____
38 Signature Date
39

40 **Reporter's Notes**

41
42 This section requires an insured to provide an authorization before an insurer may
43 acquire, use, keep, or disclose genetic information. The provisions differ from those in the
44 employment context in that insurers are permitted to continue their traditional use of family
45 medical history without special authorization requirements.

1 The draft does not disturb existing law that allows a minor to seek repudiation of consent
2 and expunge records when the minor reaches the age of majority.
3

4 *Subsection (a) General requirement for authorization.* This subsection would establish a
5 requirement that an insurer must be authorized by the insured before it may acquire, keep, or
6 disclose genetic information, except as provided elsewhere in the act. In order to give a valid
7 authorization, the insured must be informed as provided in the subsection (b) and must act
8 voluntarily. Subsection (a) also includes a requirement that an authorization must be indicated
9 by a signed record. The authorization requirement is coupled with limitations on acquisition,
10 use, retention, and disclosure in Sections 304, 305, 306, 308, and 309.
11

12 Other law of the state may provide for a substitute decisionmaker or signer if the
13 employee is incapacitated or incompetent. This situation is left to existing law of the state that
14 governs power of attorney, guardianship, or other substitute decision makers.
15

16 *Subsection (b) Obligation of recipient of authorized disclosure.* One of the difficulties in
17 authorizing disclosure is control over the information once it has been disclosed. The Drafting
18 Committee decided that regulation over the initial disclosure is ineffective without a continuing
19 obligation of confidentiality that is binding on the recipient. Hence under this subsection a
20 recipient may not redisclose the genetic information without the insured's authorization. This
21 provision extends beyond the privacy protections provided by HIPAA. States are permitted to
22 depart from HIPAA privacy provisions if they impose more stringent protections. 45 C.F.R. §
23 160.203(b).
24

25 The Committee considered and rejected several approaches to the issue, including 1) a
26 notice to the insured that the genetic information disclosed by the authorized person may be
27 subject to redisclosure by the recipient and not longer protected, and 2) a provision that an
28 insured could enter into a confidentiality agreement with recipients of their genetic information.
29

30 *Subsection (c) Content of authorization.* The provision on authorization for acquisition,
31 use, retention, or disclosure of genetic information is adapted from the HIPAA Privacy Rule
32 regulations for "uses and disclosures for which an authorization is required." 45 C.F.R. §§
33 164.508 (a) and (c), 164.512(a). The subsection adapts these regulations to apply to genetic
34 information and expands them to include authorization for acquisition and retention as well as
35 for use and disclosure.
36

37 An advantage of using the HIPAA regulations as the foundation for the authorization
38 requirements is that the requirements to authorize a disclosure by a health care provider to an
39 insurer would be similar to the requirements that health care provider must follow as a covered
40 entity under HIPAA. The context of the HIPAA regulations is different enough, however, that
41 they cannot be transported directly into the Act without modification. Moreover, states are
42 permitted to impose their own, more stringent, privacy requirements. 45 C.F.R. § 160.203(b).
43 Some have enacted statutes with different requirements for disclosing health care information,
44 which reduces the uniformity that would theoretically be achieved by using the HIPAA format.
45 Therefore, while the structure of this subsection is modeled on the HIPAA regulations, it
46 includes some additional provisions from various state statutes. *See, e.g.,* Me. Rev. Stat. Ann. tit.

1 22 § 1711-C.
2

3 *Subsection (d). Authorization form.* This subsection provides forms that may be used for
4 an insured to provide authorization for use, retention or disclosure of genetic information. Forms
5 following these examples would comply with this section.
6

7 **SECTION 311. REVOCATION OF AUTHORIZATION.**

8 (a) Except as otherwise provided in subsection (b) or by law other than this [act], an
9 insured may revoke an authorization provided under this [article] at any time in a signed record.

10 (b) An insured may not revoke an authorization provided under this [article]:

11 (1) to the extent that an insurer or other person has taken action in reliance on the
12 authorization; or

13 (2) if the authorization was granted as a condition of obtaining insurance and
14 other law provides the insurer with a right to contest a claim under, or the validity of, the policy.

15 **Reporter's Notes**
16

17 This section is adapted from the HIPAA regulation that governs revocation of an
18 authorization. 45 C.F.R. § 164.508 (b) (5). It is similar to provisions governing health care
19 information that have been adopted by some of the states. Long-term-care insurers are subject to
20 HIPAA, but life insurers and disability-income insurers are not, so this section extends the law in
21 order to give an insured greater control over his genetic information.
22

23 Other law of the state may provide for a substitute decisionmaker or signer if the
24 employee is incapacitated or incompetent. This situation is left to existing law of the state that
25 governs power of attorney, guardianship, or other substitute decision makers.
26

27 Subsection (b)(2) is included because Section 302 permits an insurer to condition the
28 availability of life, disability-income, or long-term-care insurance on an applicant's authorization
29 for a genetic test or access to genetic information about the test, if the test meets the standards of
30 Section 306 for providing a reliable prediction of mortality or morbidity. An insurer needs to
31 continue to access this information in order to protect against fraud or misrepresentation in an
32 insurance application; it has two years in which to contest the validity of the insurance contract.
33 Records are also kept for reinsurance purposes and for reapplications by the insured.
34

35 **SECTION 312. RETENTION OF AUTHORIZATION.** An insurer that receives an

1 authorization under this [article] shall keep a record of the authorization for six years after the
2 expiration date of the authorization or, if the authorization has no expiration date, for six years
3 from the date the authorization was created.

4 **Reporter’s Notes**

5
6 This section on the length of the obligation to keep an authorization is adapted from the
7 HIPAA regulations that govern documentation and retention of a signed authorization. 45 C.F.R.
8 §§ 164.508 (b) (6), § 164.530(j).
9

10 **SECTION 313. REMEDIES; ENFORCEMENT; LIMITATION OF ACTIONS.**

11 (a) An individual aggrieved by a violation of this [article] may initiate an appropriate
12 proceeding with the [state commissioner of insurance] for whatever action the [commissioner]
13 may be authorized to take under the [state unfair practice insurance law].

14 (b) An individual may initiate the administrative action authorized in subsection (a) not
15 later than two years after the individual discovers the violation of this [article] or an individual
16 exercising reasonable care should have discovered the violation.

17 *Legislative Note: States should insert for [state commissioner of insurance] the appropriate*
18 *title of this department. [The state unfair practices insurance law] should be replaced with the*
19 *title of the relevant statute.*
20

21 **Reporter’s Notes**

22
23 The draft’s remedy section is written to respond to privacy violations as well as
24 discrimination or misuse of genetic information in insurance. It has been rewritten to eliminate a
25 private right of action for an individual. An aggrieved individual may seek enforcement through
26 the State Commissioner of Insurance. An administrative remedy such as this is typical in state
27 statutes that prohibit discrimination in health insurance based on genetic testing or information.
28 These statutes declare that a violation is an unfair and deceptive insurance act or practice under
29 the state insurance code. They often provide that the State Commissioner of Insurance shall
30 enforce the prohibitions.

31
32 The Committee considered and rejected statutory damages as a remedy for a privacy
33 violation for the reason that statutory damages often serve primarily to limit recovery.

1 [ARTICLE] 4

2 MISCELLANEOUS PROVISIONS

3 SECTION 401. UNIFORMITY OF APPLICATION AND CONSTRUCTION. In
4 applying and construing this uniform act, consideration must be given to the need to promote
5 uniformity of the law with respect to its subject matter among states that enact it.

6 SECTION 402. RELATION TO ELECTRONIC SIGNATURES IN GLOBAL
7 AND NATIONAL COMMERCE ACT. This [act] modifies, limits, and supersedes the federal
8 Electronic Signatures in Global and National Commerce Act, 15 U.S.C. Section 7001, et seq.,
9 but does not modify, limit, or supersede Section 101(c) of that act, 15 U.S.C. Section 7001(c), or
10 authorize electronic delivery of any of the notices described in Section 103(b) of that act, 15
11 U.S.C. Section 7003(b).

12 SECTION 403. EFFECTIVE DATE. This [act] takes effect