

D R A F T

FOR DISCUSSION ONLY

MISUSE OF GENETIC INFORMATION IN EMPLOYMENT AND INSURANCE ACT

NATIONAL CONFERENCE OF COMMISSIONERS
ON UNIFORM LAWS

For Drafting Committee Meeting November 16-18, 2007

WITH PREFATORY AND REPORTER'S NOTES

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October 15, 2007

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MISUSE 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.

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).

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. 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.

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 vests 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 access, 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 point about preventing irrational discrimination needs elaboration. 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.

The genetic causation of most diseases 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.

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).

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. The drafting committee’s charge responds to the large number of states that have enacted legislation dealing with the threats associated with genetic information. That legislation is highly inconsistent and often deals only partially with the issues. 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.

Many of the existing state statutes on use of genetic information fall into three general categories: employment, health insurance, and other insurance, usually life, disability-income and long-term-care. There is some overlap, but often states treat each of these areas somewhat differently. Other states have statutes that cut across all three areas and govern other contexts as well. For example, statutes that concentrate on genetic testing or genetic privacy typically apply to issues of consent, disclosure, retention of samples, use of genetic material, and use of databases generally. This draft combines these approaches. Article 1 includes authorization provisions to protect privacy of genetic information in general, and these provisions are supplemented in Articles 2, 3, and 4 with specifically tailored provisions that limit testing, access, use, retention, and disclosure in employment, health insurance, and life, disability-income, and long-term-care insurance.

At this stage, Article 1 offers three alternative approaches for establishing the principles of control, consent, confidentiality and counseling in order to further the goals outlined at the beginning of the Prefatory Note. The first option would establish a principle of confidentiality and requirements for consent, which is called “authorization” to avoid confusion with the accepted medical practice of “informed consent.” This option draws its standards for privacy of genetic information from the federal regulations issued pursuant to the Health Insurance Portability and Accountability Act (HIPAA). The second and third approaches would establish a property right as a mechanism for individual control of genetic testing and genetic information.

The second option establishes a general property right and the third option establishes a property interest in the context of employment and insurance.

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 access 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 such procedures. 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). 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.” Although HIPAA includes general preemption provisions for contrary state law, state law that relates to the privacy of individually identifiable health information that are contrary to and more stringent than the federal requirements are not preempted. Thus HIPAA provides a floor, not a ceiling, for privacy protections.

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. 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.

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.

Currently federal legislation is pending that would establish specific privacy requirements for genetic information. The Genetic Information Nondiscrimination Act of 2007, S. 358 and H.R. 493, governs entities already covered by the HIPAA privacy regulations. It would prohibit these health insurers from requesting, requiring or purchasing genetic information prior to an individual’s enrollment and from using genetic information in underwriting or determining eligibility. The legislation would also limit access, use, and disclosure of genetic information by employers, labor organizations, employment agencies, and joint labor-management committees. Its provisions do not apply to life or disability-income insurers.

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).

Employment

General Policy Issues

Currently, there is no comprehensive statute or regulation that declares genetic information confidential, restricts employer access, or requires employers to protect the privacy of their employees' genetic information. 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 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.

Title VII 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 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 access to 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. Employers also have the right at that point in the hiring process to require that individuals sign a blanket release disclosing all their medical records to the employer. Employers may also test existing employees if they can justify the testing as job-related. Thus, despite the ADA’s protections against discrimination through its requirements for reasonable accommodations, the ease of employer access to medical information may deter individuals from obtaining testing.

Currently, federal legislation is pending that would increase the role of the federal government in regulating genetic testing and genetic information in employment. HR 493, the Genetic Nondiscrimination Act of 2007, was passed by the House of Representatives on April 26, 2007. A similar bill, S.358, has been reported out of committee and is pending in the Senate. The legislation contains parallel provisions that apply 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. Remedies are limited to those available under Title VII of the Civil Rights Act of 1964, the Government Employee Rights Act of 1991, the Congressional Accountability Act of 1995, Chapter 5 of Title 3 of the United States Code, or Section 717 of the Civil Rights Act of 1964. In six years, a study group will make recommendations regarding whether or not to add a cause of action for disparate treatment.

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 have built on their statutes prohibiting 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 protections 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.

Health Insurance

General Policy Issues

As in the employment arena, the treatment of genetic information by health insurers raises concerns for individuals' privacy and for how genetic information may be used by the industry. Privacy is a great concern because the health care system is where much genetic information is generated and stored.

Discrimination in health insurance is a uniquely American problem because the United States does not guarantee coverage of health care expenses for its citizens as other wealthy nations do. Legislation in this area responds to public perceptions that health insurers will deny coverage or increase premiums based on predictive genetic information. This may be irrational discrimination. In addition, individuals who fear reduced or more expensive health care coverage may avoid genetic tests that could provide useful information for improving their health. The legislative restrictions are designed to avoid these outcomes.

The main argument against regulation in this market is that genetic information would allow insurers to decrease adverse selection. Adverse selection is the disproportionate purchase of insurance by individuals who have medical reasons to believe they will need to make claims. It leads to insurer losses when applicants fail to disclose the relevant health information and it is a particular concern with individual health insurance policies. The industry and a number of scholars contend that avoiding losses due to adverse selection based on genetic information will lead to more affordable insurance.

In 1995, 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 health insurance. The recommendations apply to both group and individual health plans.

- Insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility, continuation, enrollment or contribution requirements.
- Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services.
- Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information.
- Insurance providers and other holders of genetic information 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 would be made.

Kathy Hudson et al., *Genetic Discrimination and Health Insurance: An Urgent Need for Reform*, 270 Science 392 (1995).

One study of state restrictions on the use of genetic information in health insurance concluded that there are almost no well-documented cases of insurers asking for genetic test results for pre-symptomatic conditions in either states with regulation or states without such regulation. The author argued that use of genetic information is not cost effective and is not seen by insurers as increasing the accuracy of their underwriting. Nonetheless, he believes that state laws will have an effect by making it less likely that insurers will use genetic information in the future, because the laws have helped convince insurers that use of this information is not socially acceptable. Mark A. Hall, *Legal Rules and Industry Norms: The Impact of Laws Restricting Health Insurers' Use of Genetic Information*, 40 *Jurimetrics J.* 93 (1999).

The Federal Regulatory Context

As with employment, the states legislate against the background of federal statutes governing health insurance. The 1996 Health Insurance Portability and Accountability Act (HIPAA) partially addresses the treatment and use of genetic information in health insurance. Title I amends the Employee Retirement Income Security Act (ERISA) and the Public Health Service Act with regard to availability of health insurance.

Under HIPAA's Title I provisions on availability of health insurance, an employee-sponsored group health insurance plan may not deny an applicant coverage as a result of a health-status related factor, including genetic information. Plans are specifically prohibited from using "genetic information" in establishing eligibility or benefit levels. The law also prohibits exclusions for pre-existing conditions on the basis of a genetic predisposition to a particular condition. Moreover, a plan may not restrict coverage, restrict benefits, or charge higher premiums based on the health status of an enrolled employee. Title I covers employer-sponsored group health insurance plans for 50 or more individuals, including self-insured plans. As a result, this part of HIPAA regulates only a portion of the health insurance market. It does not apply to employees in small group health insurance plans or to individual health insurance coverage.

Title II of HIPAA mandated security and privacy provisions for health care information. The Department of Health and Human Services issued regulations called the Privacy Rule, which took effect in 2003. The regulations cover "health plans," a category that includes both individual and group health insurers. It allows health insurers to disclose "protected health information," i.e., "individually identifiable health information" to facilitate treatment, payment, or health care operations. Otherwise, health insurers must first obtain authorization from the individual. 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. Insurers must notify individuals of uses of their protected health information and keep records of disclosures of that information. The Privacy Rule applies more widely than Title I because it includes individual health insurance, but there are some exceptions to its coverage that would be closed by this Act.

Pending federal legislation would specifically regulate genetic tests and the use of genetic information in the health insurance industry. As of early October 2007, S. 358 was pending in the Senate and H.R. 493 had been passed in the House of Representatives. These bills extend the protections against use of genetic information in determining eligibility or rates to the individual health insurance market and limit genetic testing by health insurers. Entities that are already covered by the HIPAA privacy regulations would be subject to specific prohibitions on the collection and use of genetic information.

Current State Statutes

The law in 47 states restricts the use of genetic information by health insurers in some way. Some states impose restrictions only on group health insurance (Ak, Iowa, SD, Wy), and some only on individual policies (Hawaii, Nebraska, WVa), but most cover both group and individual health insurance and hence have a broader reach than HIPAA's coverage provisions.

There are five main types of state regulation of genetics in health insurance. First, many states prohibit insurers from requiring individuals to have genetic tests or to disclose genetic information to the insurer. (Ark, Cal, Col, Fla, Ga, Haw, Ill, Ind, Kan, Md, Mich, Minn, Mo, Montana, Neb, NH, NMex, NY, OH, OK, Or, RI, SD, Tenn, UT, Wis). In a few states (Mich, Neb) this restriction on access to information stands alone, but most states have additional measures.

Second, a number of states prohibit health insurers from disclosing genetic information without informed consent or authorization. (Ariz, Cal, Col, Del, Ga, Haw, Ill, Ky, La, Me, Md, Mass, Mich, Mo, Nev, NH, NJ, NMex, NY, Or, RI, SC, Tenn, Tex, Vt, Va, Wash).

In addition to these privacy-based protections, there are also restrictions on health insurers' use of genetic information. In a third category, a large number of statutes provide that insurers may not establish rules for eligibility, that is, deny coverage, based on genetic information. (Alaska, Ariz, Ark, Cal, Col, Conn, Del, Fla, Ga, Haw, Ill, Ind, Iowa, Kan, Ky, La, Me, Mass, Minn, Mo, Mont, Nev, NH, NJ, NMex, NY, NC, OH, OK, Or, RI, SC, SD, Tenn, Tex, UT, Va, WVa, Wis, Wy).

Fourth, most of these same states impose some type of limit on the use of genetic information for risk selection or classification in health insurance, such as higher premiums, reduced coverage or reduced benefits. Many states simply prohibit insurers from considering genetic information for these purposes.

Fifth, some states do not permit health insurers to impose pre-existing condition exclusions based on predictive genetic information in the absence of a diagnosis based on symptoms of the disease or condition. (Alaska, Conn, Idaho, Iowa, Ky, others).

This draft does not consider the emerging health issue of access to genetic services and insurance coverage for their costs. Currently the states with laws in this area cover newborn

screening and genetic childhood diseases. According to the National Conference of State Legislatures, no state currently requires coverage of testing for adult onset genetic disorders such as breast cancer, but bills are being introduced frequently.

Life, Disability-income, 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 access to 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 access to 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

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.

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.

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 §§ 690-128.001 to 690-128.025; 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, 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).

1 **MISUSE OF GENETIC INFORMATION IN EMPLOYMENT AND INSURANCE ACT**

2
3 **ARTICLE 1**

4 **GENERAL PROVISIONS**

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

7 **Reporter’s Notes**

8
9 Some Drafting Committee members have suggested that a better title for the act would be
10 “Uniform Use of Genetic Information in Employment and Insurance Act” because the term
11 “use” includes the negative “misuse” and many of the provisions of the act permit certain uses.
12 Another suggestion by Committee members is that because the scope of the act goes beyond use
13 to include access, retention, and disclosure of genetic information, it should be titled “Uniform
14 Genetic Information in Employment and Insurance Act.”
15

16 **SECTION 102. DEFINITIONS.** In this [act]:

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

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

24 (3) “Employee” means an individual who works for compensation or who is applying to
25 work for compensation, including an individual employed in a supervisory, managerial, or
26 confidential position.

1 (4) “Employer” means a person that has an employee.

2 (5) “Family medical history” means information about the occurrence of a disease or
3 disorder in a family member of an individual.

4 (6) “Family member” means an individual’s spouse or [partner], an individual’s child,
5 and all individuals related by blood within the fourth degree of consanguinity to the individual,
6 the individual’s spouse or [partner], or the individual’s child.

7 (7) “Genetic counseling” means the process of:

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

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

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

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

17 (8) “Genetic information” means information:

18 (A) based on an individual’s genetic tests or the genetic tests of an individual’s
19 family member; or

20 (B) about an individual’s or an individual’s family member’s request for or
21 receipt of genetic services.

22 (9) “Genetic monitoring” means a periodic examination to identify or evaluate a

1 modification to genetic material, such as chromosomal damage or evidence of increased
2 occurrence of mutation, due to toxic or hazardous exposure.

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

4 (11) “Genetic test” means an analysis of human genetic material, including
5 deoxyribonucleic acid (DNA), ribonucleic acid (RNA), chromosomes, proteins, and metabolites,
6 that is intended to detect a genotype, genetic marker, mutation, or chromosomal change.

7 (12) “Health insurance” means a health care arrangement assuming financial risk to pay
8 for, purchase, or furnish health care services to patients, insureds, or beneficiaries, including:

9 (A) insurance that covers hospital, medical, or health expenses;

10 (B) an employee welfare-benefit plan;

11 (C) a health maintenance organization;

12 (D) a preferred-provider organization;

13 (E) a medical service organization;

14 (F) a physician-hospital organization;

15 (G) a self-insured health plan;

16 (H) a prepaid health-care service plan; or

17 (I) another health-care arrangement in which risk is assumed.

18 (13) “Insured” means an individual who is covered by or applying for coverage under a
19 policy of health, life, disability-income, or long-term-care insurance.

20 (14) “Insurer” means a person engaged in the business of health, life, disability-income,
21 or long-term-care insurance in this state, regardless of where a contract of insurance is written or
22 the plan is administered. The term includes an insurance agent, broker, underwriter, and third-

1 party administrator.

2 (15) “Life insurance” means insurance against the financial risk of death.

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

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

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

14 (19) “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 (20) “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 **Legislative Note:** *In the definition of “family member,” states should insert for [partner] the*
21 *appropriate term for an unmarried partner who is eligible for coverage by health insurance,*
22 *such as “domestic partner,” “significant other,” “partner,” or a similar term.*

23
24 **Reporter’s Notes**
25

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

7 *Paragraph (2). (Disability-income insurance)* This definition of disability-income
8 insurance is used in several state statutes on genetic testing. *See, e.g.*, Cal. Ins. Code § 10147;
9 N.H. Rev. Stat. Ann. § 141-H:1. The committee discussed substituting the term “income” for
10 “earning capacity,” but did not take any action.
11

12 *Paragraph (3). (Employee)* The definition of employee is adapted from the National
13 Conference of Commissioners on Uniform State Law’s Model Employment Termination Act.
14 The definition in that Act is modified by including applicants for employment within the
15 definition of employee. The definition’s requirement for compensation is intended to exclude
16 volunteers from the definition of employee.
17

18 An alternative approach suggested by the Style Committee liaison would be a separate
19 definition of “applicant” as an individual who is applying to work for compensation. This
20 suggestion was not adopted at this time because the substantive provisions of the draft do not
21 differentiate between protections for applicants and those for employees. In addition, there is a
22 potential for confusion in the substantive sections because the definition of “insured” would
23 include applicants but the definition of “employee” would not.
24

25 A second suggestion from our Style Committee liaison is to add an additional section to
26 Article I that links the treatment of applicants to that of employees. Possibilities include: “For
27 purposes of this Act, an applicant for employment is treated the same as an employee”; or “An
28 applicant for employment subject to the Act has the same rights and responsibilities as an
29 employee under the Act.”
30

31 The drafting committee considered including independent contractors in the definition of
32 employees, but decided to leave their categorization to be determined by general employment
33 law. This approach is not intended, however, to provide employers with an avenue to evade
34 their obligations by classifying employees as independent contractors.
35

36 *Paragraph (4). (Employer)* The definition of employer is linked to the definition of
37 “person” in paragraph 16 and therefore encompasses all types of entities, including
38 governmental and non-profit employers. “Employer” takes its meaning from the broad
39 definition of “employee” in paragraph 3.
40

41 As the definition of employer is currently drafted, the act would cover all employers
42 regardless of size. One consideration is whether the requirements of the act would prove too
43 burdensome for small employers. Many statutes specify a minimum size using the number of
44 employees as a proxy for size. For example, Title VII of the Civil Rights Act of 1964 covers

1 employers who had 15 or more employees for each working day in 20 or more weeks over the
2 course of a year. The definition in the Uniform Law Commissioner’s Model Employment
3 Termination Act requires five employees and extends the measurement period to two years.
4

5 Another way to limit the types of employers that are covered would be to exclude
6 immediate family members from the count of employees, as is done in the Fair Labor Standards
7 Act and the National Conference of Commissioners on Uniform State Law’s Model Employment
8 Termination Act. In addition, some state statutes exclude particular employee groups, such as
9 household workers or farm workers, in determining employer status.
10

11 *Paragraph (5). (Family medical history)* Family medical history is often a source of
12 genetic information in that it is used to evaluate the likelihood that an individual carries an
13 inherited trait. The act’s definition of “genetic information” does not encompass medical
14 history, so a separate definition is needed when the act’s provisions apply more broadly.
15

16 *Paragraph (6). (Family member)* A family member is defined broadly to encompass all
17 individuals whose own genotype could influence an employment or insurance decision. The
18 term includes (1) biological relations whose genetic information might provide information
19 about the genetic make-up of an individual employee or insured, (2) dependants whose risk of
20 future genetically-linked medical conditions could affect employer health care costs or family
21 insurance coverage and hence affect employment or insurance decisions, and (3) dependants’
22 biological relations whose genetic information might provide information about the genetic
23 make-up of a dependant. The term “dependent child” is intended to include both adopted and
24 biologically-related children because either can affect health-care costs or family insurance
25 coverage.
26

27 Many employers provide health insurance for employees’ unmarried partners. Therefore,
28 an unmarried partner can be a dependent whose risk of a genetically-linked medical condition
29 could affect employment or insurance decisions. As a result, “partner” is included in the
30 definition of family member for purposes of obtaining, retaining, using, and disclosing genetic
31 information. This definition is not meant to affect other state law definitions of marriage or
32 family. Because terminology for this status varies among the states, each state should substitute
33 its term for an unmarried partner as described in the legislative note.
34

35 *Paragraph (7). (Genetic counseling)* Genetic counseling is a key to an individual’s
36 informed decision making about getting a genetic test, understanding the result, and authorizing
37 its use, retention, or disclosure. Most states that license genetic counselors have a definition of
38 genetic counseling, but the majority of states do not license genetic counselors or regulate
39 genetic counseling. Note that the definition does not require that genetic counseling be
40 performed by a genetic counselor. Physicians and geneticists are also qualified to provide
41 genetic counseling.
42

43 The definition uses the term genetic condition, which is intended to have a broad
44 interpretation. Genetic condition includes the concepts of genetic disease and disorder, but in

1 some circumstances it may also refer to a positive or benign trait or characteristic that is linked
2 to a particular genotype.

3
4 *Paragraph (8). (Genetic information)* This definition of “genetic information” is
5 modeled on state provisions that do not include family history in the definition. (Ark, Del, LA,
6 Minn, Neb, NH, NY, OK, OR, UT, VT) This narrow definition of genetic information is
7 important for Article 4 on life, disability-income, and long-term-care insurance, in which the
8 draft allows these insurers to continue to collect information on family history, even though
9 family history is a major source of information for evaluation an individual’s genetic risks.

10
11 Many states use a more comprehensive definition of “genetic information” that includes
12 information on genetic characteristics broadly, whether obtained from genetic tests or family
13 medical history. (Cal, Conn, Hawaii, LA, Maine, MD, Mass, Mich, NJ, NMex, NC, RI, SD, TX,
14 WA). In addition, H.R. 493 and S. 358, the federal bills to prohibit discrimination on the basis
15 of genetic information with respect to health insurance and employment introduced in January
16 2007, also use a broad definition. The federal definition provides that the term means
17 “information about (i) an individual’s genetic tests; (ii) the genetic tests of family members of
18 the individual; or (iii) the occurrence of a disease of disorder in family members of the
19 individual.” Information about the sex or age of an individual is excluded from this definition.

20
21 The drafting committee has endorsed using the broader meaning, including family
22 history, for Articles 2 and 3 on employment and health insurance. This meaning is conveyed in
23 these articles by combining the narrowly defined term “genetic information” with the term
24 “family medical history.”

25
26 Information about an individual’s request for or receipt of genetic services is included in
27 the category of genetic information for ease of drafting.

28
29 *Paragraph (9). (Genetic monitoring)* The definition of “genetic monitoring” is drawn
30 from the description in Office of Technology Assessment, *Genetic Monitoring and Screening in*
31 *the Workplace* 4 (1990). The focus in monitoring is not on inherited characteristics, but on
32 genetic alterations in a group of exposed individuals over time. Genetic monitoring is typically
33 undertaken by employers to identify risks for groups of employees who have been exposed to
34 hazardous substances or to target work sites for safety and health measures. Testing for this
35 purpose is permitted in Section 201.

36
37 *Paragraph (10). (Genetic service)* “Genetic service” is a broader category than genetic
38 testing. The term includes activities associated with obtaining genetic information that could
39 create assumptions about an individual’s genetic status even in the absence of information about
40 genetic test results or medical history. “Counseling” implies a one-on-one consultation, so the
41 definition also includes “genetic education” in order to capture group information sessions on
42 genetic conditions. Members of the drafting committee have expressed concern, however, that
43 “education” may make the definition too broad. While the definition of a “genetic service” does
44 not separately define the term “genetic,” the term should be interpreted to be consistent with the

1 definitions of “genetic test” and “genetic information.”
2

3 *Paragraph (11). (Genetic test)* “Genetic test” is defined in terms of (1) the purpose of the
4 test and (2) the material that the test analyzes. This structure and the lists in the definition are
5 derived from the definition of “genetic test” in the medical insurance provisions of H.R. 493 and
6 S. 358, federal bills to prohibit discrimination on the basis of genetic information with respect to
7 health insurance and employment introduced in January 2007.
8

9 The first sentence specifies that the test must be for the purpose of determining an
10 individual’s genetic make-up through the identification of a genotype, genetic marker, mutation,
11 or chromosomal change. The second sentence makes specific reference to the types of biological
12 material that are currently analyzed in genetic tests. Note that genetic tests can be conducted
13 not only on gene sequences, but also on biological products such as proteins or metabolites that
14 can indicate genetic make-up.
15

16 Both sentences are equally important to the definition. First, some of the materials listed
17 in the second sentence, especially proteins and metabolites, are tested for many medical
18 purposes. A test of a protein or metabolite does not constitute a genetic test unless it is
19 administered for the purpose of determining individual’s genetic make-up as specified in the first
20 sentence. Second, some genetic diagnoses are made without laboratory tests of the type listed in
21 the second sentence. For example, a doctor may identify a genetic condition based on specific
22 physical features occurring in combination, or “dismorphology.” This physical diagnosis of an
23 individual’s genetic-make-up does not constitute a genetic test under the draft because it is not a
24 test of “genetic material.”
25

26 The draft follows the example of states with definitions of genetic testing that are not
27 limited to identifying genotypes associated with diseases or impairments. (Fla, Haw, Mass, NH,
28 Ore, UT). In contrast, many other states statutes limit their definition of “genetic test” to testing
29 for disease-related genes. (Ariz, Ark, Del, Ill, Iowa, Kan, LA, Maine, MD, Mich, Minn, Nev,
30 MO, Neb, NJ, NM, NY, NC, OK, OR, RI, TX, VT, VA, WI). While most of the reasons that an
31 employer or insurer might currently seek or use genetic information probably involve a disease,
32 disorder, or impairment, this may not always be the case. One can imagine, for example, that the
33 presence or absence of behavioral traits might also be a criterion for selecting an employee.
34 While the current evidence linking behavior to genes is tenuous, this area continues to be the
35 subject of investigation. Moreover, a broad definition of “genetic test” will facilitate the
36 application of the statute to topics outside employment and insurance, if that is the direction the
37 National Conference of Commissioners on Uniform State Laws takes. For example, provisions
38 governing the retention of samples used for research or identification would cover testing that is
39 not necessarily linked to disease.
40

41 *Paragraph (12). (Health insurance)* The definition of “health insurance” is meant to be
42 broad. Definitions and terms of art vary greatly among the states. For example, a number of
43 states use the term “disability insurance” for what is commonly thought of as “health insurance.”
44 The definition is written in terms of functions and organizational structures and is intended to

1 capture the full range of health insurance without regard to specific state designations. It adopts
2 the broad framework used in Ala. Code § 27-53-1(3), supplemented with terms for health care
3 arrangements used in other states. In addition, the definition includes a “health care arrangement
4 in which risk is assumed,” which serves as a catch-all category. This concept is drawn from Fla.
5 Stat. § 627.4301.
6

7 *Paragraph (13). (Insured)* The definition of “insured” is intended to cover applicants for
8 insurance as well as those covered by insurance policies.
9

10 *Paragraph (14). (Insurer)* The definition of “insurer” is intended to cover broadly
11 insurance companies and other persons and individuals that issue health, life, disability-income,
12 or long-term-care insurance and all persons who might obtain, use, or disclose genetic
13 information associated with that process. Nothing in this definition is intended to subject
14 insurance agents, brokers, underwriters, or third-party administrators to insurance regulations to
15 which they are not already subject.
16

17 *Paragraph (15). (Life insurance)* “Life insurance” is intended to be defined broadly.
18 This definition is drawn from N.H. Rev. Stat. § 401:1(III).
19

20 *Paragraph (16). (Long-term-care insurance)* The starting point for the definition of
21 “long-term-care insurance” is N.H. Rev. Stat. § 415-D:3(V). The definition is intended to
22 include all coverage of this nature whether it is provided on an expense-incurred, indemnity,
23 prepaid, or other basis.
24

25 *Paragraph (17). (Person)* This draft uses the broad version of the standard National
26 Conference of Commissioners on Uniform State Laws definition of “person.”
27

28 *Paragraph (18). (Predisposing genetic characteristic)* A “predisposing genetic
29 characteristic” refers to an genotype that signals an increased risk of a certain disease or
30 condition. The term does not include symptomatic diseases or conditions or genetic
31 characteristics that are manifest in a disease, medical condition, or disability. The broader terms
32 “genetic test” and “genetic information” may include both predisposing and manifest genetic
33 characteristics as well as genetic information that does not necessarily pertain to health.
34

35 While the terms “propensity” or “susceptibility” are often used, the actual manifestation
36 of a disease or condition may depend on a complex chain of events and the degree to which risk
37 is elevated may be quite small. “Predisposing genetic characteristic” is meant to signal the
38 tenuous connection between a genotype or marker and a physical manifestation.
39

40 *Paragraph (19). (Record)* The definition of “record” is the standard National Conference
41 of Commissioners on Uniform State Laws definition.
42

43 *Paragraph (20). (Sign)* The definition of “sign” is the standard National Conference of
44 Commissioners on Uniform State Laws definition.

1
2
3 **ALTERNATIVE PRIVACY APPROACHES**
4 **FOR DRAFTING COMMITTEE CONSIDERATION**

5 **Reporter's Notes**

6
7 The Drafting Committee requested alternative approaches for maintaining privacy for
8 genetic testing and genetic information.
9

10 Alternative A would protect privacy by establishing an authorization requirement that is
11 coupled with statutory limits and duties imposed on employers, employment agencies, labor
12 organizations, licensing authorities, and insurers. Under this alternative, an employee or insured
13 must affirmatively authorize any genetic testing (§ 103) or access, use, retention, or disclosure of
14 genetic information or family medical history (§ 104). The authorization requirement is not
15 simply an extra procedural step because Articles 2, 3, and 4 establish limitations on the situations
16 in which employers and insurers may request authorization from employees or insureds .
17

18 Alternative B would establish a general property right in a biological sample an
19 individual provides for genetic testing and in the resulting genetic information (§ 103(a)). It is
20 coupled with an authorization requirement (§ 103(b)). Like Alternative A, it sets forth the
21 elements that must be included in an authorization (§ 104).
22

23 Alternative C is a modification of Alternative B that attempts to establish a limited
24 property applicable only to the context of employment and insurance.
25

26 More detailed reporter's notes follow each set of alternative provisions.
27

28 **Alternative A**

29 **SECTION 103. AUTHORIZATION FOR A GENETIC TEST.**

30 (a) Except as otherwise provided by this [act] or otherwise provided by law, if a genetic
31 test is permitted by Section 201 or 401 and the test is authorized by an employee or insured
32 following genetic counseling, an employer, employment agency, labor organization, or licensing
33 authority may provide the test. The employee's or insured's authorization for the genetic test
34 must be knowing and voluntary and indicated by a record signed by the employee or insured.
35 When an employer, employment agency, labor organization, licensing authority, or insurer

1 receives a valid authorization to provide a genetic test, the test must be consistent with the
2 authorization.

3 (b) An authorization for a genetic test for employment must:

4 (1) inform the employee that the employer, employment agency, labor
5 organization, or licensing authority is obligated to provide genetic counseling before the
6 employee considers the authorization;

7 (2) inform the employee that genetic counseling is available for the employee
8 about the risks and benefits of the test before signing the authorization and about the test result
9 after the test, unless the employee directs otherwise;

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

12 (4) include an opportunity for the employee to provide directions about reporting
13 test results and genetic counseling;

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

15 (6) inform the employee that only the authorized genetic test will be performed on
16 the employee's biological sample;

17 (7) inform the employee that the employee's biological sample will be destroyed
18 as soon as permitted by law following the completion of the test unless the employee authorizes
19 retention of the sample or unless otherwise ordered by a court, arbitral tribunal, or administrative
20 agency; and

21 (8) state that the employee is entitled to a copy of the authorization form.

22 (c) An authorization for a genetic test for life, disability-income, or long-term-care

1 insurance must:

2 (1) inform the insured that the insured should obtain genetic counseling before
3 considering the authorization;

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

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

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

9 (5) inform the insured that only the authorized genetic test will be performed on
10 the insured's biological sample;

11 (6) inform the insured that the insured's biological sample will be destroyed as
12 soon as permitted by law following the completion of the test unless the insured authorizes
13 retention of the sample or unless otherwise ordered by a court, arbitral tribunal, or administrative
14 agency; and

15 (7) state that the insured is entitled to a copy of the authorization form.

16 **SECTION 104. AUTHORIZATION FOR ACCESS, RETENTION, OR**
17 **DISCLOSURE OF GENETIC INFORMATION OR FAMILY MEDICAL HISTORY.**

18 (a) Except as otherwise provided by this [act] or otherwise provided by law, an
19 employer, employment agency, labor organization, licensing authority, or insurer may not
20 access, use, retain, or disclose an employee's or insured's genetic information or family medical
21 history without the employee's or insured's knowing and voluntary authorization indicated by a
22 record signed and dated by the employee or insured. When an employer, employment agency,

1 labor organization, licensing authority, or insurer receives a valid authorization to access, use,
2 retain, or disclose genetic information or family medical history, its access, use, retention, or
3 disclosure must be consistent with the authorization.

4 (b) An authorization to access, use, retain, or disclose an employee's or insured's genetic
5 information or family medical history must:

6 (1) Describe the genetic information or family medical history to be accessed,
7 used, retained, or disclosed in a specific and meaningful fashion;

8 (2) Identify or describe the person that is authorized to access, use, retain, or
9 disclose the genetic information or family medical history;

10 (3) If the authorization is for access to genetic information or family medical
11 history through disclosure by another person to an employer, employment agency, labor
12 organization, licensing authority, or insurer, identify or describe the person authorized to make
13 the disclosure;

14 (4) If the authorization is for use of genetic information or family medical history,
15 describe the permitted uses;

16 (5) If the authorization is for retention of genetic information or family medical
17 history, describe where the information will be retained and identify or describe the custodian of
18 the information;

19 (6) If the authorization is for disclosure to a third person, identify or describe the
20 third person to whom the authorized person may disclose the genetic information or family
21 medical history;

22 (7) If the authorization is for disclosure to a third person, state that the genetic

1 information or family medical history disclosed by the authorized person may be subject to
2 redisclosure by the recipient and no longer be protected.

3 (8) Indicate the duration of the authorization with an expiration date or expiration
4 event that relates to the employee or insured or to the purpose of the access, use, retention, or
5 disclosure;

6 (9) State that the employee or insured may revoke the authorization at any time in
7 a signed record, subject to the right of a person who acted in reliance on the authorization prior
8 to receiving notice of revocation, and provide instructions on how to revoke an authorization;
9 and

10 (10) State that the employee or insured is entitled to a copy of the authorization
11 form.

12 **Reporter's Notes**

13 **Alternative A**

14
15
16 *Section 103: Authorization for genetic testing.* This section deals with genetic testing. It
17 sets forth an authorization requirement and the elements that must be contained in an
18 authorization form. The term "authorization" is used instead of "informed consent" to avoid
19 confusion with the use of that term in medical practice.
20

21 *Subsection (a) Requirement for authorization for genetic testing.* Under Section 201, an
22 employer, employment agency, labor organization, or licensing authority may supply genetic
23 tests under certain circumstances but only with prior authorization from the employee. Under
24 Section 401, an insurer may require a genetic test as a condition of obtaining life, disability-
25 income, or long-term-care insurance if the test has been approved under Section 404. Under this
26 subsection, genetic testing allowed by these sections is permitted only if an employee or insured
27 first authorizes the genetic test.
28

29 In order to meet the requirement that an authorization be knowing and voluntary, an
30 employee or insured should have genetic counseling before signing the authorization. Genetic
31 counseling provides employees or insureds with adequate information to make an informed
32 decision about genetic testing. It also makes them aware of their options regarding reporting of
33 test results and help in interpreting them through genetic counseling. An employer, employment

1 agency, labor organization, or licensing authority that offers a genetic test has an obligation to
2 provide genetic counseling under Section 201(c). Genetic counseling may be provided by a
3 genetic counselor, but may also be provided by a qualified physician or geneticist.
4

5 *Subsections (b) and (c) Content of authorization for testing.* The section draws on N.Y.
6 Civ. Rights Law § 79-1 (McKinney), which establishes requirements for consent for a genetic
7 test. Subsection (b) applies in the employment context and subsection (c) applies to insurance.
8

9 The requirements in subsection (b)(1)-(4) reflect the obligation of the employer,
10 employment agency, labor organization, or licensing authority to provide genetic counseling
11 under Section 201(c). The insurance provision in subsection (c) does not require the insurer to
12 provide genetic counseling, but to inform the insured that it is desirable.
13

14 The limitation in (b)(6) and (c)(5) to the authorized test is consistent with the
15 requirements for prior authorization in Sections 201 and 401.
16

17 The notification provision for retention of the sample in (b)(7) and (c)(6) is consistent
18 with the employer's or insurer's obligation to ensure the sample is destroyed under Section
19 201(c)(3) or 401(b)(3), which recognize that the testing laboratory may be required to retain the
20 sample for certification purposes.
21

22 *Section 104: Authorization for access, use, retention, or disclosure.* This section
23 requires an employee or insured to provide an authorization before an employer, employment
24 agency, labor organization, licensing authority, or insured may access, use, retain or disclose
25 genetic information or family medical history. While the section makes general reference to
26 both genetic information and family medical history, Article 4 narrows the restrictions for life,
27 income-disability, and long-term-care insurers. While their access, use, retention and disclosure
28 of genetic information is limited, they are permitted to continue their traditional use of family
29 medical history.
30

31 The draft does not disturb existing law that allows a minor to seek repudiation of consent
32 and expunge records when the minor reaches the age of majority.
33

34 *Subsection (a) General requirement for authorization.* This subsection would establish a
35 requirement that an employer, employment agency, labor organization, licensing authority, or
36 insurer must be authorized by the employee or insured before it may access, retain, or disclose
37 genetic information, except as provided elsewhere in the act. In order to give a valid
38 authorization, the employee or insured must be informed as provided in the following
39 subsections and must act voluntarily. This subsection also includes a requirement that an
40 authorization must be indicated by a signed and dated record. This authorization requirement is
41 coupled with limitations on access, use, retention, and disclosure in Articles 2 and 4.
42

43 If an individual is deceased and unable to provide authorization for disclosure, the
44 individual's personal representative may provide the authorization. This might be desirable if an

1 individual’s relatives seek genetic information that might be relevant to their genetic traits. In
2 the event of legal incapacity, a guardian or other person authorized by state law to make
3 decisions on behalf of the individual may revoke the authorization for disclosure.
4

5 *Subsection (b) Content of authorization.* Alternative A’s provision on authorization for
6 access, use, retention, or disclosure of genetic information or family medical history is adapted
7 from the HIPAA Privacy Rule regulations for “uses and disclosures for which an authorization is
8 required.” 45 C.F.R. §§ 164.508 (a) and (c), 164.512(a). The subsection adapts these
9 regulations to apply to genetic information and family medical history, and expands them to
10 include authorization for access and retention as well as for use and disclosure.
11

12 An advantage of using the HIPAA regulations as the foundation for the authorization
13 requirements is that the requirements to authorize a disclosure by a health care provider to an
14 employer, employment agency, labor organization, licensing authority, or insurer would be
15 similar to the requirements that health care provider must follow as a covered entity under
16 HIPAA. The context of the HIPAA regulations is different enough, however, that they cannot be
17 transported directly into the Act without modification. Moreover, states are permitted to impose
18 their own, more stringent, privacy requirements. 45 C.F.R. § 160.203(b). Some have enacted
19 statutes with different requirements for disclosing health care information, which reduces the
20 uniformity that would theoretically be achieved by using the HIPAA format. Therefore, while
21 the structure of this subsection is modeled on the HIPAA regulations, it includes some additional
22 provisions from various state statutes. *See, e.g.,* Me. Rev. Stat. Ann. tit. 22 § 1711-C.
23

24 **Alternative B – General Property Right**

25 **SECTION 103. PROPERTY RIGHT.**

26 (a) Except as provided in subsection (c), an individual’s biological sample provided for a
27 genetic test and the genetic information based on the test are the exclusive property of the
28 individual.

29 (b) Except as provided in subsection (c), a person may not collect a biological sample for
30 a genetic test from an individual, provide a genetic test, or access, use, retain, or disclose an
31 individual’s genetic information or family medical history without first obtaining the
32 individual’s authorization as provided in Section 104. When a person receives a valid
33 authorization to test for, access, use, retain, or disclose genetic information or family medical

1 history, its test, access, use, retention, or disclosure must be consistent with the authorization.

2 (c) Subsections (a) and (b) do not apply to biological samples collected or tests
3 conducted:

4 (1) pursuant to [the State criminal DNA identification statute] or a comparable
5 provision of another jurisdiction;

6 (2) for a law enforcement purpose;

7 (3) to determine paternity;

8 (4) to screen newborn babies as required by state or federal law; or

9 (5) for the purpose of emergency medical treatment.

10 *Legislative Note: States should replace [the State criminal DNA identification statute] with the*
11 *title of the relevant statute.*
12

13 **SECTION 104. REQUIRED AUTHORIZATIONS.**

14 (a) An authorization to collect a biological sample for a genetic test from an individual,
15 provide a genetic test, or access, use, retain, or disclose an individual's genetic information or
16 family medical history must be indicated in a record signed and dated by the individual.

17 (b) An authorization to collect a biological sample and perform a genetic test must:

18 (1) inform the individual that the authorized person is obligated to provide genetic
19 counseling before the individual considers the authorization;

20 (2) inform the individual that genetic counseling is available for the individual
21 about the risks and benefits of the test before signing the authorization and about the test result
22 after the test, unless the individual directs otherwise;

23 (3) inform the individual that the test result will be reported to the individual and

1 a health-care professional designated by the individual, unless the individual directs otherwise;

2 (4) include an opportunity for the individual to provide directions about reporting
3 test results and genetic counseling;

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

5 (6) inform the individual that only the authorized genetic test will be performed
6 on the individual's biological sample;

7 (7) inform the individual that the individual's biological sample will be destroyed
8 as soon as permitted by law following the completion of the test unless the individual authorizes
9 retention of the sample or unless otherwise ordered by a court, arbitral tribunal, or administrative
10 agency; and

11 (8) state that the individual is entitled to a copy of the authorization form.

12 (c) An authorization to access, use, retain, or disclose an individual's genetic information
13 or family medical history must:

14 (1) Describe the genetic information or family medical history to be accessed,
15 used, retained, or disclosed in a specific and meaningful fashion;

16 (2) Identify or describe the person that is authorized to access, use, retain, or
17 disclose the genetic information or family medical history;

18 (3) If the authorization is for access to genetic information or family medical
19 history through disclosure by another person to an employer, employment agency, labor
20 organization, licensing authority, or insurer, identify or describe the person authorized to make
21 the disclosure;

22 (4) If the authorization is for use of genetic information or family medical history,

1 describe the permitted uses;

2 (5) If the authorization is for retention or genetic information or family medical
3 history, describe where the information will be retained and identify or describe the custodian of
4 the information;

5 (6) If the authorization is for disclosure to a third person, identify or describe the
6 third person to whom the authorized person may disclose the genetic information or family
7 medical history;

8 (7) If the authorization is for disclosure to a third person, state that the genetic
9 information or family medical history disclosed by the authorized person may be subject to
10 redisclosure by the recipient and no longer be protected.

11 (8) Indicate the duration of the authorization with an expiration date or expiration
12 event that relates to the employee or insured or to the purpose of the access, use, retention, or
13 disclosure;

14 (9) State that the individual may revoke the authorization at any time in a signed
15 record, subject to the right of a person who acted in reliance on the authorization prior to
16 receiving notice of revocation, and provide instructions on how to revoke an authorization; and

17 (10) State that the individual is entitled to a copy of the authorization form.

18 **Reporter's Notes**

19 **Alternative B**

20
21
22 *Section 103: Property Right.* This section declares that an individual has a property
23 right in the individual's sample provided for genetic testing and in the genetic information based
24 on that testing. In Alternative B, the property right is not limited to the context of employment
25 or insurance. The property right in subsection (a) is coupled with a requirement in subsection (b)
26 that the individual's must authorize any genetic testing or access, use, retention, or disclosure of
27 the individual's genetic information. This authorization requirement also extends to an

1 individual’s family medical history, although that is not included in the property right.
2

3 The state laws that create a property right in genetic information (Alaska and Florida)
4 provide exceptions for situations in which authorization is not required. The same is true for the
5 other states that impose a general requirement for authorization for genetic testing or for access,
6 use, retention, or disclosure of genetic information. Subsection (c) provides the exceptions
7 typically included in those state statutes. Section 103 is based on Alaska Stat. § 18.13.010.
8

9 *Subsection (a) Property Right.* A property right is a bundle of rights including rights that
10 permit the owner to use, donate, sell, or exclude others from using the object of the right.
11 Because much personal property can be given away without any process of informed consent or
12 formal authorization, merely conferring a property right in genetic information, without more,
13 does not necessarily ensure control, confidentiality, consent, and counseling. This is why the
14 property right is coupled with an authorization requirement similar to that in Alternative A.
15

16 What a property right adds beyond what would be achieved by a statutory limitations on
17 testing, access, use, retention and disclosure coupled with a duty for employers and insurers to
18 act in accordance with an employee’s or insured’s authorization is (1) a symbolic emphasis on
19 the rights of the individual; (2) a right to alienate the property; and (3) the availability of a
20 conversion action. (Although the right to alienate can be limited, as in the case of selling body
21 organs.)
22

23 The right to alienate a biological sample for genetic testing or genetic information is most
24 relevant in the context of research on genetic conditions and the development of tests or
25 therapies. Courts that have considered the issue have refused to recognize a property right in this
26 situation. For example, families with children afflicted with Canavan disease who hoped for a
27 broadly available diagnostic test provided biological samples, confidential information, and
28 financial support to a researcher, which led to the isolation of the gene responsible for the
29 disease. The Miami Children’s Hospital patented the Canavan gene and thus obtained the ability
30 to restrict activity related to the gene, including carrier and prenatal testing, gene therapy, and
31 the gene’s use in other research. When the hospital began to limit testing by restrictive licensing
32 of the patent, family members sued unsuccessfully to prevent the hospital from enforcing its
33 patent rights. They alleged, among other causes of action, that they had a property interest in
34 their bodily tissue and genetic information. The court refused to find a property right in body
35 tissue and genetic matter donated for research and denied their claim of conversion. *Greenberg*
36 *v. Miami Children’s Hospital Research Institute*, 264 F. Supp. 2d 1064, 1074-76 (S.D. Fla.
37 2003). The court noted that under Florida law property rights in blood and tissue samples
38 “evaporate[] once the sample is given voluntarily to a third party.” *Id.* at 1075. *See also*
39 *Washington University v. Catalona*, 2007 WL 1758268 (8th Cir. June 20, 2007) (finding that
40 “individuals who made an informed decision to contribute their biological materials voluntarily
41 to a particular research institution” did not “retain an ownership interest allowing the individuals
42 to direct or authorize the transfer of such materials to a third party”); *Moore v. Regents of the*
43 *University of California*, 793 P. 2d 479 (Cal. 1990) (refusing to recognize donor’s ownership of
44 cells used in research).

1 If the families in the *Greenberg* case had possessed a statutory property right in the
2 samples and information, they could have licensed their use of the samples and information for
3 research. To achieve their goals, they could have restricted the license to require that any
4 diagnostic test the research produced must be accessible on affordable basis and that the research
5 would remain in the public domain to promote further research on prevention and treatment.
6 Alternatively, if they had profit goals, they could have constructed a license that would provide
7 them with a share of the patent license fees.
8

9 It is not clear, however, that a property right is necessary in this context. Other patient
10 groups have accomplished similar goals by contract. For example, PXE International is a patient
11 group for sufferers of pseudoxanthoma elasticum, a genetic disorder that causes connective tissue
12 in arteries, skin, and eyes to calcify. The group set up a tissue bank from families afflicted with
13 the disease, which they made available to researchers under a contract that required the
14 researchers to share the ownership and profits from the research. When the PXW gene was
15 discovered, the patent application listed the founder of PXE International as a co-inventor. The
16 patient organization shares royalties equally with the research institution and controls licensing
17 arrangements for the gene patent. Matt Fleisher, *Seeking Rights to Crucial Genes*, National Law
18 Journal, June 25, 2001 at C1.
19

20 This issue of a property right in genetic information is not whether such a right can exist,
21 but how it arises and who holds it. It is certainly possible for a researcher to obtain a property
22 right in the isolated sequence of a gene in the form of a patent. *See, e.g.*, U.S. Department of
23 Energy Office of Science, Office of Biological and Environmental Research, Human Genome
24 Program, Genetics and Patenting, <https://www.ornl.gov/hgmis/elsi/patents.html>. A patent is a
25 limited property right that permits the holder to exclude others from using the genetic sequence.
26 It does not, however, necessarily permit the inventor to use the patented materials if another
27 holds and invokes a relevant “upstream” patent to exclude the inventor from using the invention
28 or to control that use via the terms of a license. This is the context in which courts have held that
29 an individual who donates a sample does not “own” the sample or the genetic information
30 derived from that sample. If an individual did hold a property right in her genetic information,
31 she would be able to exert control over “downstream” uses through a conversion action. There
32 are arguments that the field of genetics is already burdened with excessive upstream rights under
33 the current patent rules. *See* Michael Haller & Rebecca S. Eisenberg, *Can Patents Deter*
34 *Innovation? The Anticommons in Biomedical Research*, 280 Science 698 (1998). Courts that
35 have rejected a property right in donated biomedical material have expressed a similar concern.
36 *See, e.g., Moore v. Regents of the University of California*, 793 P. 2d 479, 494 (Cal. 1990) (“The
37 extension of conversion law into this area will hinder research by restricting access to the
38 necessary raw materials.”). In contrast, dissenters have questioned why the individual who is the
39 source of the material should not be able to share in the economic benefits of the research or,
40 more broadly, determine the use of the material before it is donated. *See id.* at 500, 505
41 (Broussard, J., concurring and dissenting); *id.* at 513-16 (Mosk, J., dissenting).
42

43 It is not clear that the conversion action the plaintiffs sought to bring in the *Moore* and
44 *Greenberg* cases, which would be available if there were a property right, would be very useful

1 to employees or insureds. The normal remedy for conversion is replevin, but returning genetic
2 information to an employee or insured would not erase the employer's or insurer's knowledge or
3 reverse the harm. Damages would have been a useful remedy to provide the donors with a share
4 of the economic benefits of the patents. But in the context of employment or insurance, damages
5 for the privacy violation would be very hard to prove.
6

7 Employees and insureds are not concerned with sharing the economic proceeds of an
8 invention, but with their ability to exclude employers and insurers from accessing or using
9 genetic information, and to condition the terms on which they may access and use it. Can an
10 individual control the terms of access, use, retention, and disclosure of genetic information by
11 contract, as in the PEX example? Or is a property right necessary? There was no need for a
12 recognized property right in the PEX situation because the patient group had control of
13 information that was valuable to the researchers and had bargaining power to dictate the terms
14 on which researchers accessed and used the information. An at-will employee or an applicant
15 for insurance does not have the same bargaining power when asked to provide genetic
16 information as a condition of work or an insurance policy. One question for the drafting
17 committee to consider is whether declaring a property right would, by itself, change that power
18 balance.
19

20 Power balances can also be shifted by creating rights other than property rights. To
21 exclude an employer or insurer from accessing or using genetic information, an employee or
22 insured needs a right to deny access and use without any correlative right on the part of the
23 employer or insurer to access or use the information. To control the access and use of genetic
24 information, an employee or insured needs a right to exercise authority over that access and use,
25 coupled with a corresponding duty on the part of employers and insurers to obey that authority.
26 Another question for the drafting committee is whether it would be sufficient to establish a
27 statutory obligation that employers and insurers may not require genetic tests or obtain genetic
28 information as a condition of providing employment or insurance, coupled with a requirement
29 for authorizations to control an employer's or insurer's range of action with regard to genetic
30 information.
31

32 *Subsection (b) Requirement for authorization.* The property right established in
33 subsection (a) can be shared, donated, or discarded. Therefore if an individual wants to provide
34 genetic information, but maintain control over who may access it and how it is used, an
35 additional mechanism is necessary. The state statutes that establish a property right in genetic
36 information couple it with a similar authorization requirement.
37

38 *Subsection (c) Exceptions.* A general property right would restrict many uses of genetic
39 information with social value. This subsection represents a determination that the property right
40 should be limited in certain context where the social value derived from the ability to access an
41 individual's genetic information out weighs the importance of the property right. The list of
42 exceptions is common to many of the state statutes with a general authorization requirement.
43

1 Some states also except the use of an individual’s genetic information in medical
2 research from the property right. Genetic research is an additional use that would be impeded by
3 an individual property right. If the Drafting Committee decides to include a property right in the
4 Act, more work will need to be done on this complicated issue.

5
6 *Section 104: Authorization content.* This section is similar to the authorization
7 provisions in Sections 103 and 104 of Alternative A.
8

9 **Alternative C – Narrower Property Right**

10 **SECTION 103. PROPERTY RIGHT.**

11 (a) An employee or insured who provides a biological sample for a genetic test or genetic
12 information to an employer, employment agency, labor organization, licensing authority, or
13 insurer is the owner of the sample or information.

14 (b) An employer, employment agency, labor organization, licensing authority, or insurer
15 may not collect a biological sample for a genetic test from an employee or insured, provide a
16 genetic test, or access, use, retain, or disclose an employee’s or insured’s genetic information or
17 family medical history without first obtaining the employee’s or insured’s authorization as
18 provided in Section 104. When an employer, employment agency, labor organization, licensing
19 authority, or insurer receives a valid authorization to test for, access, use, retain, or disclose
20 genetic information or family medical history, its test, access, use, retention, or disclosure must
21 be consistent with the authorization.

22 **SECTION 104. REQUIRED AUTHORIZATIONS.**

23 (a) An authorization to collect a biological sample for a genetic test from an employee or
24 insured, perform a genetic test, or access, use, retain, or disclose an employee’s or insured’s
25 genetic information or family medical history must be indicated in a record signed and dated by
26 the employee or insured.

1 (b) An authorization to collect a biological sample and perform a genetic test for
2 employment must:

3 (1) inform the employee that the authorized person is obligated to provide genetic
4 counseling before the employee considers the authorization;

5 (2) inform the employee that genetic counseling is available for the employee
6 about the risks and benefits of the test before signing the authorization and about the test result
7 after the test, unless the employee directs otherwise;

8 (3) inform the employee that the test result will be reported to the employee and a
9 health-care professional designated by the employee, unless the employee directs otherwise;

10 (4) include an opportunity for the employee to provide directions about reporting
11 test results and genetic counseling;

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

13 (6) inform the employee that only the authorized genetic test will be performed on
14 the employee's biological sample;

15 (7) inform the employee that the employee's biological sample will be destroyed
16 as soon as permitted by law following the completion of the test unless the employee authorizes
17 retention of the sample or unless otherwise ordered by a court, arbitral tribunal, or administrative
18 agency; and

19 (8) state that the employee is entitled to a copy of the authorization form.

20 (c) An authorization for a genetic test for life, disability-income, or long-term-care
21 insurance must:

1 (1) inform the insured that the insured should obtain genetic counseling before
2 considering the authorization;

3 (2) inform the insured that the test result will be reported to the insured and a
4 health-care professional designated by the insured, unless the insured directs otherwise;

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

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

8 (5) inform the insured that only the authorized genetic test will be performed on
9 the insured's biological sample;

10 (6) inform the insured that the insured's biological sample will be destroyed as
11 soon as permitted by law following the completion of the test unless the insured authorizes
12 retention of the sample or unless otherwise ordered by a court, arbitral tribunal, or administrative
13 agency; and

14 (7) state that the insured is entitled to a copy of the authorization form.

15 (d) An authorization to access, use, retain, or disclose an employee's or insured's genetic
16 information or family medical history must:

17 (1) Describe the genetic information or family medical history to be accessed,
18 used, retained, or disclosed in a specific and meaningful fashion;

19 (2) Identify or describe the person that is authorized to access, use, retain, or
20 disclose the genetic information or family medical history;

21 (3) If the authorization is for access to genetic information or family medical
22 history through disclosure by another person to an employer, employment agency, labor

1 organization, licensing authority, or insurer, identify or describe the person authorized to make
2 the disclosure;

3 (4) If the authorization is for use of genetic information or family medical history,
4 describe the permitted uses;

5 (5) If the authorization is for retention of genetic information or family medical
6 history, describe where the information will be retained and identify or describe the custodian of
7 the information;

8 (6) If the authorization is for disclosure to a third person, identify or describe the
9 third person to whom the authorized person may disclose the genetic information or family
10 medical history;

11 (7) If the authorization is for disclosure to a third person, state that the genetic
12 information or family medical history disclosed by the authorized person may be subject to
13 redisclosure by the recipient and no longer be protected;

14 (8) Indicate the duration of the authorization with an expiration date or expiration
15 event that relates to the employee or insured or to the purpose of the access, use, retention, or
16 disclosure;

17 (9) State that the employee or insured may revoke the authorization at any time in
18 a signed record, subject to the right of a person who acted in reliance on the authorization prior
19 to receiving notice of revocation, and provide instructions on how to revoke an authorization;
20 and

21 (10) State that the employee or insured is entitled to a copy of the authorization
22 form.

1 **Reporter's Notes**

2
3 **Alternative C**

4
5 Alternative C provides a narrower property right in genetic information that is limited to
6 the context of employment and insurance, the scope assigned to the Drafting Committee. It is
7 not clear, however, that such a right could be created effectively in isolation, in the absence of a
8 more comprehensive property right in genetic information.

9
10 If it is possible to create a property right limited to employment and insurance, it is
11 unnecessary to establish exceptions for situations outside the employment and insurance context
12 in which public policy concerns outweigh privacy concerns, such as those provided in § 103(c)
13 of Alternative B. Otherwise, Alternative C is parallel to Alternative B but phrased more
14 narrowly in terms of employees and insureds.

15 **End of Alternatives**

16 **SECTION 105. REVOCATION OF AN AUTHORIZATION.**

17 (a) Except as provided in subsection (b), an employee or insured may revoke an
18 authorization provided under this [Article] at any time in a signed record.

19 (b) An employee or insured may not revoke an authorization provided under this
20 [Article]:

21 (1) to the extent that an employer, employment agency, labor organization,
22 licensing authority, or insurer has taken action in reliance on the authorization; or

23 (2) if the authorization was granted as a condition of obtaining insurance, other
24 law provides the insurer with a right to contest a claim under the policy.

25 **Reporter's Notes**

26
27 This section is adapted from the HIPAA regulation that governs revocation of an
28 authorization. 45 C.F.R. § 164.508 (b) (5). It is similar to provisions governing health care
29 information that have been adopted by some of the states.

30
31 Under the prior draft, an employee or insured could revoke authorization for retention at
32 any time. A drafting committee member suggested that revocations should apply only to future
33 records. Instead, this draft limits revocation on grounds used in the HIPAA privacy regulations.

1 If an individual is deceased and unable to revoke authorization, the individual’s personal
2 representative may revoke the authorization. In the event of legal incapacity, a guardian or other
3 person authorized by state law to make decisions on behalf of the individual may revoke the
4 authorization.
5

6 Subsection (b)(2) is included because under this draft Article 4 would permit an insurer
7 to condition the availability of life, disability-income, or long-term-care insurance on an
8 applicant’s authorization for a genetic test, if the test has been certified as providing a reliable
9 prediction of mortality or morbidity.
10

11 **SECTION 106. RETENTION OF AUTHORIZATION.** An employer, employment
12 agency, labor organization, licensing authority, or insurer that receives an authorization under
13 this section must retain a record of that authorization for six years from the date of its creation or
14 the date when it was last in effect, whichever is later.

15 **Reporter’s Notes**
16

17 This section on the length of the obligation to retain an authorization is adapted from the
18 HIPAA regulations that govern documentation and retention of a signed authorization. 45
19 C.F.R. §§ 164.508 (b) (6), § 164.530(j). Special requirements that apply when an employer
20 retains genetic information are set forth in Section 206.

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ARTICLE 2

EMPLOYMENT

SECTION 201. GENETIC TESTING SUPPLIED FOR EMPLOYMENT.

(a) Except as otherwise provided in this section, an employer, employment agency, labor organization, or licensing authority may not offer or supply a genetic test to an employee.

(b) An employer, employment agency, labor organization, or licensing authority may offer a genetic test and, with prior authorization of the employee that meets the requirements of Section 104, may supply a genetic test to the employee:

(1) to determine the employee’s predisposing genetic characteristics that may create susceptibility to harm to the employee from a workplace condition;

(2) to monitor the effects of the employees’ exposure to a workplace condition as part of a genetic monitoring program; or

(3) as part of a confidential, preventative health program for employees.

(c) An employer, employment agency, labor organization, or licensing authority that supplies a genetic test to an employee shall:

(1) provide for genetic counseling for the employee about the risks and benefits of the genetic test before the employee considers authorizing the test and about the test result unless the employee directs otherwise;

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

1 (3) require that the employee’s biological sample obtained for a genetic test be
2 destroyed as soon as permitted by law following the completion of the test unless the employee
3 authorizes retention of the sample or unless otherwise ordered by a court, arbitral tribunal, or
4 administrative agency.

5 (d) If a court, arbitral tribunal, or administrative agency orders an employee to undergo a
6 genetic test under Section 202 (d), the employer, employment agency, labor organization, or
7 licensing authority shall provide and pay for the genetic test for the employee.

8 **Reporter’s Notes**
9

10 *Applicability of Article 2.* This article is intended to apply broadly in the employment
11 setting to an employer, employment agency, labor organization, or licensing authority.
12 Employment agencies, labor organizations, and licensing authorities are included because they
13 control access to employment through referrals or licensing.
14

15 *Relationship between genetic testing and access to genetic information.* Genetic testing
16 is a means by which an employer can obtain genetic information, but it is also possible for
17 employers to supply testing without gaining access to individualized test results. Therefore the
18 draft separates provisions on employer access to genetic information, treated in Section 202,
19 from the provisions in this section on genetic testing. An employer should supply testing
20 through an outside medical organization. See Mark A. Rothstein, *Genetics and the Workforce of*
21 *the Next Hundred Years*, 2000 Colum. Bus. L. Rev. 371 (2000).
22

23 *Genetic testing.* Many states broadly prohibit employers from subjecting employees to
24 genetic testing. See, e.g., Iowa Code Ann. § 729.6 (employer may not “solicit, require, or
25 administer” a genetic test as a condition of employment); Kan. Stat. Ann. § 44-1009(a)(9)
26 (employer may not subject, directly or indirectly, any employee to any genetic screening or test);
27 Md. Code Art. 49B § 16(a) (employer may not “request or require” genetic tests as a condition
28 for hiring or determining benefits); Mass. Gen. L. Art. 151B § 4(19) (unlawful to “solicit
29 submission to, require, or administer a genetic test” as a condition of employment); Mich. Comp.
30 Laws § 37.1202 (no employer may require a genetic test as a condition of employment); Minn.
31 Stat. Ann. § 181.974(subd. 2) (employer may not “administer a genetic test” as a condition of
32 employment); Neb. Rev. Stat. § 48-236 (employer may not require a genetic test as a condition
33 or employment or promotion); Nev. Rev. Stat. § 613.345 (unlawful employment practice to
34 “require or administer” a genetic test as a condition of employment); N.H. Rev. Stat. § 141-H
35 (may not “solicit, require, or administer” genetic testing as a condition of employment); RI Stat.
36 § 28-6.7-1 (employer may not “request, require, or administer” a genetic test); Utah Code Ann. §
37 26-45-103 (employer may not “request or require” an individual or blood relative to submit to a

1 genetic test in connection with an employment decision); Vt. Stat. Ann. § 9333 (may not require
2 genetic testing as a condition of employment); Va. Code Ann. § 40.1-28.7-1 (employer may not
3 “request, require, solicit, or administer” a genetic test as a condition of employment); Wash.
4 Rev. Code Ann. § 49.44.180 (unlawful to require employee to submit to genetic screening as
5 condition of employment); Wis. Stat. Ann. § 111.372 (employer may not “solicit, require, or
6 administer” a genetic test as a condition of employment unless employee requests test). This
7 section does not prohibit testing entirely, but limits the purposes for which an employer may
8 provide a genetic test.
9

10 *Subsection (a) General prohibition on genetic testing.* The general rule is that an
11 employer, employment agency, labor organization, or licensing authority may not offer or
12 provide genetic tests to employees. The other subsections establish limited exceptions and set
13 requirements for counseling and reporting that must be met if a genetic test is provided.
14

15 *Subsection (b) Acceptable purposes for an employer to supply genetic tests.* The draft
16 permits employers to offer genetic testing for three purposes: to determine predisposing
17 characteristics that may create susceptibility for harm to the employee due to workplace
18 conditions, to monitor exposure to workplace conditions as part of an ongoing program, and as
19 part of a confidential preventative health program for employees.
20

21 The drafting committee considered, but did not adopt, a provision that would permit
22 employers to supply genetic testing in order to protect the safety of other employees in the
23 workplace. It would be very rare for a genetic marker to indicate a safety threat to other
24 employees with sufficient certainty to justify a genetic test. The draft does not limit an
25 employer’s ability to take an employee’s manifested medical condition into account for safety
26 purposes, subject to the provisions of the Americans With Disabilities Act.
27

28 *Subsection (b)(1) Employee susceptibility.* Determining employee susceptibility to harm
29 from exposure to workplace substances, called “genetic screening,” is one situation in which
30 some states have permitted employers to test with the consent of the employee. Iowa, Louisiana,
31 New Hampshire, New York, and Wisconsin all have nearly identical provisions that permit
32 genetic testing of an employee to determine an employee’s susceptibility to toxic substances if
33 the employee requests testing, provides informed consent or authorization, and the employer
34 does not terminate the employee or take other adverse action as a result of testing. Iowa Code
35 Ann. § 729.6(7); N.H. Rev. Stat. § 141-H:3; N.Y. Exec. Law § 296; Wis. Stat. Ann. § 111.372.
36

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

1 so, testing could provide information that could define an individual's risk from workplace
2 exposure to beryllium.

3
4 The draft allows an employer to supply testing for such susceptibilities, but unless the
5 employee volunteers the test results under Section 202(b), the employer is not authorized to
6 obtain them.

7
8 *Subsection (b)(2) Genetic monitoring program.* Monitoring for damage to employees'
9 genes from workplace exposure to harmful substances is another possible justification for
10 testing. The states that permit an employer to screen for genetic susceptibility to harmful
11 workplace substances also permit monitoring for exposure provided the employee requests
12 testing, provides informed consent or authorization, and the employer does not terminate the
13 employee or take other adverse action as a result of testing. Iowa Code Ann. § 729.6(7); N.H.
14 Rev. Stat. § 141-H:3; N.Y. Exec. Law § 296; Wis. Stat. Ann. § 111.372. In addition, Louisiana
15 authorizes monitoring of biological effects of toxic substances in the workplace if the employee
16 has provided authorization and is notified of the results. La. Rev. Stat. § 23:368. More
17 generally, the definitions and prohibitions in many state's statutes do not appear to restrict
18 monitoring for genetic damage, or are ambiguous on this issue.

19
20 Genetic damage is caused by mutagens, that is, substances that are capable of triggering
21 change in the genetic material of a cell. Genetic damage appears in the form of recessive and
22 dominant mutations, large rearrangements of DNA, point mutations, or loss of genetic material.
23 Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* 71
24 (1990).

25
26 There are multiple genetic tests for exposure to mutagens at both the chromosomal and
27 molecular level. The most common indicators of chromosomal (cytogenic) damage are
28 chromosomal aberrations (CAs) and sister chromatid exchanges (SCEs). CAs are chromosomes
29 with breakage or rearrangements. *Id.* at 62. CAs are more likely to be induced by ionizing
30 radiation than chemical agents, but there are notable exceptions. For example, vinyl chloride
31 exposure results in increased CAs and places workers at risk of developing a form of liver
32 cancer. Workers exposed to benzene show elevated CAs and are at increased risk of leukemia.
33 *Id.* at 65. Sister chromatids are the two daughter strands of a duplicated chromosome. An
34 exchange results when apparently equivalent sections of the sister chromatids of the same
35 chromosome are switched during cell division. SCE is a sensitive marker for DNA damage and
36 repair that results only from chemical mutagens, not from radiation. *Id.* at 63.

37
38 As of 1990, no occupational studies had directly connected chromosomal abnormalities
39 to increased individual risk for disease. Thus, while CA and SCE monitoring may have
40 predictive value for a group, it is not a reliable way to predict health risks for an individual. *Id.*
41 at 66. Monitoring can, however, be used by employers to reduce exposures to known mutagens
42 to a level that does not affect individuals' chromosome morphology or DNA. Data on CAs are
43 routinely used by regulatory agencies in the process of setting exposure standards for industry.
44 *Id.*

1 There are also new techniques that measure exposure to mutagens at the molecular level.
2 They include measuring the frequency of lymphocytes (T-cells) in which the HPRT gene has
3 been inactivated by mutation; detecting DNA “adducts” (an alteration in which exogenous
4 material is bound to DNA); determining DNA repair (which indicates excision damage);
5 measuring the DNA content of cells as a means to detect tumors (which contain cells with
6 elevated levels of chromosomes); and detecting oncogenes (cancer-causing genes), which can be
7 activated by damage such as translocations, breaks, and deletions of DNA. *Id.* at 66-69. There
8 is a potential that detecting activated oncogenes and DNA adducts may eventually provide a
9 method for predicting disease in asymptomatic individuals. *Id.* at 71.

10
11 This draft recognizes the utility of monitoring in the workplace using such tests, and
12 permits employers to supply genetic testing as part of a genetic monitoring program. Employers
13 may not, however, have access to test results except in the aggregate, non-individually
14 identifiable form prescribed in Section 202(c).

15
16 *Subsection (b)(3) Employee health plan.* An employer that provides preventative health
17 services to encourage a healthy workplace may include genetic testing as part of those services.
18 The test results would not be available to the employer unless the employee volunteers them
19 under section 202(a).

20
21 *Subsection (c) Conditions for testing.*

22
23 *Subsection (c)(1) Genetic counseling.* The draft requires employers to provide genetic
24 counseling in two settings unless the employee declines the counseling. First, the employee
25 must be offered genetic counseling about the risks and benefits of the test before signing the
26 authorization for testing, so that the employee can make an informed decision about whether or
27 not to have the test. Second, the draft provides for reporting test results to a health care
28 professional and mandates the availability of genetic counseling so that the results can be
29 interpreted for the employee.

30
31 Employer-provided genetic counseling should normally be conducted by professionals –
32 typically genetic counselors, geneticists, or physicians – from outside the employer organization.

33
34
35 *Subsection (c) (2) Reporting test results.* This subsection provides for reporting genetic
36 test results to the employee when an employer supplies testing. The reporting obligation is
37 incurred whether or not the employer may obtain the test results under Section 202. An
38 employer must be sensitive, however, to the fact that not all individuals wish to know their
39 genetic information. The draft recognizes an employee’s right to decline to know the results of a
40 genetic test. An employee may not wish to be informed of the result because of the
41 psychological burdens that may accompany such knowledge.

42
43 *Subsection (c)(3) Destruction of the sample obtained for testing.* The provision for
44 prompt destruction of a sample obtained for genetic testing supplied by an employer protects the

1 employee’s privacy by preventing subsequent testing of the sample. It also recognizes, however,
2 that a testing laboratory is required to retain samples for certain time periods for certification
3 testing and other purposes. The provision follows statutes adopted in New Jersey and Oregon.
4

5 Alternative approaches (1) put the burden on the employee by requiring that the sample
6 be destroyed promptly on the request of the individual tested or (2) specify that a sample may be
7 retained for a period of time. Some provisions combine elements of more than one approach. In
8 New York, for example, a sample may be retained for ten years if authorized by the individual
9 from whom the sample was obtained.
10

11 *Subsection (d) Legal proceedings.* This subsection requires an employer to supply the
12 genetic testing when a court, arbitral tribunal, or administrative agency has ordered that an
13 employer may obtain genetic information relevant to a claim or defense in a legal proceeding
14 under subsection 202(d).
15

16 **SECTION 202. ACCESS TO GENETIC INFORMATION FOR EMPLOYMENT.**

17 (a) Except as otherwise provided in this section, an employer, employment agency, labor
18 organization, or licensing authority may not knowingly obtain or directly or indirectly inquire
19 about, request, or require an employee to provide an employee’s genetic information or family
20 medical history.

21 (b) An employer, employment agency, labor organization, or licensing authority may
22 access an employee’s genetic information or family medical history if the employee voluntarily
23 submits the genetic information or family medical history to the employer, employment agency,
24 labor organization, or licensing authority. If an employee voluntarily submits genetic
25 information or family medical history retained by a source other than the employee, the
26 employee’s authorization must satisfy the requirements of Section 104.

27 (c) If an employer, employment agency, labor organization, or licensing authority offers
28 a genetic test as part of a genetic monitoring program under Section 201, the employer,

1 employment agency, labor organization, or licensing authority must receive the genetic test
2 results in an aggregate form that does not disclose individually identifiable information.

3 (d) An employer, employment agency, labor organization, or licensing authority may
4 obtain genetic information or family medical history about an employee without the employee's
5 authorization if:

6 (1) the employee has placed the employee's health at issue in a judicial, arbitral,
7 or administrative agency proceeding in which the employer, employment agency, labor
8 organization, or licensing authority is a defendant;

9 (2) the genetic information or family medical history is relevant to a claim or
10 defense in the proceeding; and

11 (3) on a motion by the employer, employment agency, labor organization, or
12 licensing authority a court, arbitral tribunal, or administrative agency orders the employee to
13 undergo a genetic test or provide genetic information or family medical history after finding that
14 the employer, employment agency, labor organization, or licensing authority has demonstrated
15 compelling need and that the information is otherwise unavailable.

16 **Reporter's Notes**

17
18 *Existing state law.* An employer, employment agency, labor organization, or licensing
19 authority gets health information in a variety of ways including applications, interviews,
20 references, post-offer medical exams, post-offer releases of medical records, Family and Medical
21 Leave Act requests, workers' compensation claims, health insurance claims to self-insured
22 employers, and voluntary disclosures by employees. Many states have tried to limit employer
23 access to genetic information. There are statutes that prohibit an employer from requiring,
24 requesting, or administering genetic testing, obtaining genetic information, making inquiries
25 about genetic information, or some combination of these methods of accessing genetic
26 information. (Conn, Del, Iowa, Kan, MD, Mass, Mich, Minn, Neb, Nev, NH, NY, OR, RI, Tex,
27 UT, VT, VA, WA, WI).
28

1 *Privacy rationale.* One rationale for limiting employer access to genetic information is
2 the view that an employee should be able to keep genetic information private. At least one state
3 has a constitutional right of privacy that appears to be relevant to genetic information. (Alaska)
4 Another rationale is to make genetic discrimination less likely. Unlike discrimination based on
5 sex or race, an employer cannot discriminate on the basis of genetic characteristics unless it has
6 access to genetic information.

7
8 Scholars have argued that a privacy rationale makes more sense for protecting genetic
9 information in the employment context than an anti-discrimination rationale. Statutory
10 protections based on anti-discrimination rationales are designed for socially-recognized groups
11 that have been historically disadvantaged. Genetic variations do not fit especially well within
12 this paradigm. *See, e.g.,* Pauline T. Kim, *Genetic Discrimination, Genetic Privacy: Rethinking*
13 *Employee Protections for a Brave New Workplace*, 96 NW U. L. Rev. 1497 (2002).

14
15 *Subsection (a) Access to genetic information.* The draft permits an employer,
16 employment agency, labor organization, or licensing authority to access genetic information
17 about an employee at the employee’s instigation only. This follows the approach of a number of
18 states that restrict an employer’s ability to require or obtain genetic information. *See, e.g.,* Conn.
19 Stat. Ann. § 46a-60(11) (employer may not “request or require” genetic information from
20 employee); Kan. Stat. Ann. § 44-1009(a)(9) (employer may not seek to obtain, obtain, or use
21 testing information to distinguish employees or restrict a right or benefit); La. Rev. Stat. §
22 23:368 (employer may not “require, collect, or purchase” protected genetic information with
23 respect to an employee); Md. Code Art. 49B § 16(a) (employer may not “request or require”
24 genetic information as a condition for hiring or determining benefits); Mass. Gen. L. Art. 151B §
25 4(19) (unlawful to “collect, solicit or require disclosure of genetic information” as a condition of
26 employment); Mich. Comp. Laws § 37.1202 (no employer may “directly or indirectly acquire or
27 have access to” an employee’s or family member’s genetic information unless an individual
28 provides it voluntarily); Minn. Stat. Ann. § 181.974(subd. 2) (employer may not “request,
29 require, or collect” protected genetic information as a condition of employment); Neb. Rev. Stat.
30 § 48-236 (employer may not require genetic information as a condition of employment or
31 promotion); Utah Code Ann. § 26-45-103 (employer may not “access or otherwise take into
32 consideration” private genetic information in connection with an employment decision); Wash.
33 Rev. Code Ann. § 49.44.180 (unlawful to require employee to submit genetic information as
34 condition of employment).

35
36 The draft also allows employees to keep private information that could lead to
37 discrimination based on assumptions about genetics, even in the absence of genetic information.
38 It does this by including information about requests for or receipt of genetic services in the
39 definition of genetic information. If an individual is unable to keep private his use of genetic
40 services such as counseling, the individual may be deterred from obtaining this service for fear
41 that an employer will assume the employee has reason to think he has a genetic disorder.

42
43 The draft follows a number of state statutes that prohibit employers from accessing or
44 using information about an employee’s request for or use of genetic services. *See, e.g.,* La. Rev.

1 Stat. § 23:368 (employer may not “require, collect, or purchase” information about an
2 employee’s request for or use of genetic services); Maine Rev. Stat. Ann. § 19302 (employer
3 may not discriminate on basis that an individual received a genetic test or genetic counseling
4 except when based on a bona fide occupational qualification); N.C. Gen. Stat. Ann. § 95-28.1A
5 (unlawful to deny employment of account of request for genetic testing or counseling services);
6 Utah Code Ann. § 26-45-103 (employer may not inquire into whether an individual or blood
7 relative has taken or refused to take a genetic test); Vt. Stat. Ann. § 9333 (employer may not use
8 the fact that genetic counseling or tested services have been requested or performed).
9

10 The draft’s approach to employer access is in contrast to that of anti-discrimination
11 statutes, which typically allow employers to compel testing or to require employees to provide
12 genetic information under certain circumstances. Most of the states that rely on disability
13 statutes to regulate genetic information follow the Americans with Disabilities Act (ADA),
14 which permits an employer to test an applicant and access an applicant’s medical records after a
15 conditional offer of employment. 29 C.F.R. § 1630.14(b). This approach opens the door broadly
16 to genetic information once an employer has made a conditional offer of employment. In
17 addition, under the ADA and most state statutes modeled on it, after an employee is hired, an
18 employer can obtain medical information if it has a reasonable belief that the employee is unable
19 to perform the essential functions of his or her job due to a medical condition. 29 C.F.R. §
20 1630.14(c). States that have amended their employment discrimination statutes to include
21 genetics usually follow the rubric of these statutes and permit genetic testing or collection of
22 genetic information when it is relevant to “job-related qualifications” or justified by “business
23 necessity.”
24

25 The draft’s approach also contrasts with California’s and Minnesota’s more
26 comprehensive limitations on employer access, which prohibit employers from accessing non-
27 job related medical information at any time. An advantage of California’s and Minnesota’s
28 approach is that it does not depend on how “genetic information” is defined. In addition, it does
29 not rely on custodians of medical files to make a distinction between genetic information and
30 medical information more generally, which are usually mixed in medical files. Practically
31 speaking, when an employee signs a release permitting employer access to medical records,
32 everything in the records is included. There are those who maintain that legislation is needed to
33 limit an employer’s ability to obtain any non-job-related health information during the hiring
34 process or employment. See Mark A. Rothstien, *Genetic Exceptionalism and Legislative*
35 *Pragmatism*, 35 Hastings Center Report No. 4 (2005), at 35. The drafting committee discussed
36 this approach, but declined to adopt it because it extends beyond the scope granted to the
37 committee. In addition, members of the drafting committee were concerned that tying the Act’s
38 protections to the concept of “job-related” medical information would not provide adequate
39 protection for genetic information. In interpreting the ADA, some courts have interpreted that
40 category broadly to permit employers to access medical information, thus narrowing the scope of
41 protection.
42

43 The prohibition on seeking or inquiring genetic information is not intended to prevent an
44 employer from informing an employee about the availability of a genetic test that is relevant to

1 conditions in the workplace or from informing an employee about a genetic monitoring program.
2
3

4 If an employee authorizes employer access to genetic information, the conditions under
5 which an employee grants that authorization are important. Some states permit employers to
6 request genetic information under the apparent assumption that an employee's consent to an
7 employer's request is voluntary. It is possible, however, to argue that in the context of at-will
8 employment, the need to retain one's job may turn an employer's request for genetic information
9 into a demand that an employee dare not refuse. Thus some statutes prohibit even requests or
10 inquiries. *See, e.g.,* Mass. Gen. L. Art. 151B § 4(19) (unlawful to "question a person about their
11 genetic information or genetic information concerning their family members"); Nev. Rev. Stat. §
12 613.345 (unlawful employment practice to "ask or encourage" an employee to submit to a
13 genetic test). This draft follows that approach.
14

15 A more stringent level of protection could protect workers from ever providing genetic
16 information or authorizing access, even on their own initiative. But a blanket prohibition on any
17 disclosure arguably goes too far. It would prevent an employee from sharing information that
18 could be used to protect the person from situations in which the employee is genetically
19 susceptible to harm. In addition, it would make it easy to violate the act inadvertently by
20 disclosing information an employee does not realize is genetic information. Instead, this draft
21 follows a middle approach that permits employees to volunteer genetic information, but does not
22 generally permit employers to require it.
23

24 *Subsection (b) Voluntary provision.* Employees who provide genetic information
25 voluntarily may do so directly, through oral statements or by turning over reports of test results.
26 They may also do so by permitting an employer to see medical records held by a third party. In
27 the case of disclosures made by a third party to an employer, the draft requires prior
28 authorization by the employee. The prohibition on employer inquiries is intended to apply to
29 inquires directed to other entities as well as to inquiries directed to the employee.
30

31 A complication left unresolved in this draft is that employers who have access to medical
32 records (which is permitted under the ADA after a conditional offer of employment or during
33 employment for job-related purposes) will have access to genetic information because it is
34 interspersed throughout medical records. An employer that requests any medical information is
35 likely to receive the entire file, including genetic information. The committee considered the
36 fact that mental health records are kept separate from medical records and HIPAA requires a
37 separate authorization before they can be disclosed. However, mental health records are not
38 determined by the content of the record, but as those kept by a psychologist or psychiatrist. The
39 committee considered, but rejected, requiring genetic tests to be kept in a separate record. An
40 alternative solution would be to develop technologies that can limit the scope of information
41 disclosed by health care providers. Mark A. Rothstein & Meghan Talbott, *Compelled Disclosure*
42 *of Health Information: Protecting Against the Greatest Potential Threat to Privacy*, 295 JAMA
43 2882 (2006).
44

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

11
12 This subsection permits employers to access genetic information as part of a genetic
13 monitoring program. Section 201 permits an employer to offer employees genetic tests as part of
14 a monitoring program and Section 204 permits employers to use genetic information for
15 monitoring purposes. The rationale for genetic monitoring programs is discussed in more depth
16 in the Reporter's notes to section 201.

17
18 *Subsection (d) Legal proceedings.* This draft provides for an employer to obtain an
19 employee's genetic information if the employee places his health at issue in a legal proceeding.
20 This right is limited in that it applies only if the employer has satisfied the burden of proof to
21 show compelling need and that the information is otherwise unavailable. Only that portion of an
22 employee's genetic information that is relevant to a claim or defense may be provided. This
23 subsection is meant to operate in conjunction with subsection 204(a)(2), which permits an
24 employer to use genetic information in a legal proceeding. Subsection 201(c) requires the
25 employer to pay for this test. These procedures provide more protection than Rule 35 of the
26 Federal Rules of Civil Procedure or state equivalents, which provide that a court may order a
27 physical examination on motion for good cause shown. The drafting committee considered a
28 requirement that the genetic test results be sealed or placed under a protective order, but decided
29 to leave this to existing law.

30
31 The substance of the subsection follows Utah's statute, which authorizes genetic testing
32 when an employee has placed his or her health at issue in a proceeding, but only by order of a
33 court or administrative agency after finding compelling need and that the information is
34 otherwise unavailable. Utah Code Ann. § 26-45-103(2). Other states have more narrowly
35 authorized employer testing to investigate a workers' compensation claim. (NH, NY).

37 **SECTION 203. MISUSE OF GENETIC INFORMATION IN EMPLOYMENT.**

38 Except as otherwise provided in Section 204(a), an employer, employment agency, labor
39 organization, or licensing authority may not take an adverse employment action against an
40 employee based on the employee's genetic information or family medical history.

1
2
3 **Reporter’s Notes**

4 Many state statutes limit use of genetic information by prohibiting discrimination among
5 employees or applicants for employment on the basis of genetic information. (Ark, Ill, Kan, LA,
6 Maine, MD, Mass, Mich, MO, Neb, Nev, NJ, NY, NC, OK, OR, RI, SD, Tex). Others more
7 generally ban any use of genetic information in employment. For example, New Mexico’s 2005
8 statute provides simply that “[i]t is unlawful for a person to use genetic information in
9 employment,” In Utah, employers may not take into account genetic information about an
10 individual in connection with an employment decision. Similarly, in Iowa, an employer may not
11 use genetic information to “affect the terms, conditions, or privileges of employment” of a
12 person who gets a genetic test. Iowa Code Ann. § 729.6(2).

13 This draft follows the example of Minnesota and Wisconsin, which prohibit adverse
14 employment actions based on genetic information. Minn. Stat. § 181.974 subd. 2(a)(2) (may not
15 “affect the terms or conditions of employment or terminate the employment of any person based
16 on protected genetic information”); Wis. Stat. § 111.375 (may not “affect terms, conditions or
17 privileges of employment, labor organization membership or licensure or terminate the
18 employment labor organization membership or licensure”). The term used in the draft, “adverse
19 employment decision” is a term of art in employment law that does not need to be defined in this
20 act.

21
22 This restriction on employment actions is particularly important because of uncertainty
23 about how courts will apply federal statutes to decisions based on genetic information that
24 predicts employee susceptibility to harm from workplace exposures. On one hand, in 1991 the
25 United States Supreme Court held that a chemical company’s policy barring women of child-
26 bearing age from employment opportunities that involved exposure to lead violated Title VII
27 prohibitions on gender discrimination. *International Union v. Johnson Controls*, 499 U.S. 187
28 (1991). On the other hand, the ADA allows employers to act on health information, even in the
29 case of disability, when there is a direct threat to the health or safety of others in the workplace.
30 The Equal Employment Opportunity Commission (EEOC) has interpreted this ADA provision to
31 apply when there is no risk to others but when an employer can show that an individual’s
32 disability poses a significant risk of harm to the individual. The United States Supreme Court
33 upheld this interpretation. *Chevron v. Echazabal*, 122 S. Ct. 2045 (2002). Although the
34 *Echazabal* case did not involve a genetic characteristic, but rather a worker’s liver damage due to
35 exposure to workplace solvents, the implication of the case is that in the absence of a prohibition
36 in a state statute, an employer may make adverse employment decisions based on genetic
37 screening or monitoring requested by an employee even if there is no threat to others. This
38 section, in conjunction with section 204(a), would not permit an employer to take an adverse
39 employment action unless an employee has a genetic characteristic that creates a direct threat of
40 harm to others. Harm to the employee is not a justification. As a result, employers would not be
41 able to use an employee’s genetic information in the way the employee’s health information was
42 used in the *Echazabal* case.

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

13 **SECTION 204. AUTHORIZED USE OF GENETIC INFORMATION IN**
14 **EMPLOYMENT.**

15 (a) An employer, employment agency, labor organization, or licensing authority that
16 obtains genetic information or family medical history in compliance with Section 202 may use
17 the genetic information or family medical history to:

18 (1) protect the health or safety of others from a direct threat of harm created by an
19 employee’s genetic characteristic;

20 (2) monitor the effects of employees’ exposure to a workplace condition as part
21 of a genetic monitoring program; or

22 (3) defend a claim in a judicial, arbitral, or administrative proceeding in which an
23 employee has placed the employee’s health at issue.

24 (b) An employer, employment agency, labor organization, or licensing authority that
25 obtains genetic information or family medical history in compliance with Section 202 about an
26 employee’s predisposing genetic characteristic that may create susceptibility to harm to the
27 employee from a workplace condition may use the genetic information or family medical history
28 to reduce the employee’s exposure to the workplace condition.

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Reporter's Notes

The draft selectively authorizes ways that an employer may use genetic information in employment decisions about individual employees.

Subsection (a)(1). Direct threat to health or safety of others. The Americans with Disabilities Act permits employers to establish qualification standards that include a requirement that employees shall not pose a “direct threat to the health or safety of other individuals in the workplace.” 42 U.S.C. § 12113(b). This draft incorporates that concept, but broadens it beyond threats to others in the workplace by extending it to threats to others generally, including others who are outside the workplace. The drafters intend to incorporate current judicial interpretations of the term “direct threat,” which require a risk of severe and imminent harm. It is conceivable that some manifest genetic conditions might create a direct threat in some circumstances and if an employee volunteers genetic information that indicates a threat of the required severity and imminence, an employer may act to protect the health and safety of others. (Mich, Neb). While theoretically possible, it would be extremely rare for a predisposing genetic characteristic to create this type of threat and the drafting committee has been unable to identify any known genetic trait that would qualify.

Subsections (a)(2) and (a)(3). Monitoring programs or legal proceedings. This subsection permits an employer to use genetic information for a monitoring program or defending a legal proceeding, which is consistent with the purposes for which an employer may access an employee’s genetic information under Section 202.

Subsection (b). Employee susceptibility to harm in the workplace. This subsection, in combination with section 203, follows the lead of the states that permit genetic testing to determine susceptibility to harm from a workplace substance only when an employer does not use the information to terminate or take other adverse action against the employee. See Iowa Code Ann. § 729.6(7); N.H. Rev. Stat. § 141-H:3; N.Y. Exec. Law § 296; Wis. Stat. Ann. § 111.372. An employer may offer genetic testing to screen for susceptibility to harm under section 201, but may not access the results of the testing. If an employee volunteers genetic information about susceptibility to harm from workplace exposures under section 202, the draft permits the employer to reduce the potentially harmful exposure, but not to make an employment decision that would adversely affect the employee.

The Brush-Wellman company in Cleveland, Ohio, developed a program (since discontinued) that provides a model for permissible use of screening or monitoring information. Brush-Wellman conducted genetic tests for its employees who work with beryllium, but the testing was voluntary and confidential. Moreover, the test results were provided to the employee, who made the decision on what action to take. The company took no action against the employee as a result of the genetic testing. Cynthia Nance, Paul Miller, & Mark Rothstein, *Discrimination in Employment on the Basis of Genetics*, 6 Employee Rights & Employment Policy Journal 57, 64-65 (2002).

1 **SECTION 205. ACCESS TO GENETIC INFORMATION BY AN EMPLOYEE.**

2 (a) Except as provided in subsection (b), an employee may inspect, request correction of,
3 or obtain a copy of the employee’s genetic information or family medical history from any
4 record of an employer, employment agency, labor organization, or licensing authority which
5 contains the information. If an employee requests correction of genetic information or family
6 medical history, the employer, employment agency, labor organization, or licensing authority
7 must include the request for correction and supporting data in the employee’s record.

8 (b) Except as otherwise provided by law, an employee may not access genetic
9 information or family medical history compiled in reasonable anticipation of, or for use in, a
10 civil, criminal, arbitral, or administrative proceeding.

11 **Reporter’s Notes**

12
13 This section is based on the conclusion that an employee ought to be able to find out
14 what genetic information an employer knows about an employee and to have the same
15 information. It is based on 16 Del. Code § 1223. It also provides a mechanism for an employee
16 to correct genetic information contained in employer records.

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

22
23 The section makes an exception for information compiled for litigation, except to the
24 extent the employee has a right of access under the discovery rules. This exception is drawn
25 from the HIPAA Privacy Rule. 45 C.F.R. § 164.524.
26

27 **SECTION 206. CONFIDENTIALITY; RETENTION AND DISCLOSURE OF**
28 **GENETIC INFORMATION IN EMPLOYMENT.**

29 (a) Except as provided in subsection (e), an employer, employment agency, labor
30 organization, or licensing authority shall treat an employee’s genetic information, family medical

1 history, or authorization for an employer, employment agency, labor organization, or licensing
2 authority to supply genetic testing or to obtain, retain, or disclose genetic information as a
3 confidential record.

4 (b) Except as provided in subsection (e), if an employee authorizes an employer,
5 employment agency, labor organization, or licensing authority to retain a record of an
6 employee's genetic information or family medical history, the employer, employment agency,
7 labor organization, or licensing authority shall retain the record or require the record to be
8 retained separately from the employee's personnel files.

9 (c) If an employee authorizes an employer, employment agency, labor organization, or
10 licensing authority to supply genetic testing or to access, retain, or disclose genetic information
11 or family medical history, the employer, employment agency, labor organization, or licensing
12 authority shall retain the authorization or require the authorization to be retained separately from
13 the employee's personnel files.

14 (d) Except as provided in subsection (e) or as necessary to defend a claim in a judicial,
15 arbitral, or administrative proceeding, an employer, employment agency, labor organization, or
16 licensing authority may not disclose an employee's individually identifiable genetic information
17 to a person other than the employee unless the employee authorizes the disclosure or unless
18 otherwise ordered by a court, arbitral tribunal, or administrative agency.

19 (e) This section does not apply to an employee's genetic information obtained in
20 aggregate form pursuant to Section 202(c) for use in a genetic monitoring program.

21 **Reporter's Notes**

22
23 *Subsection (a) Confidentiality.* This subsection declares that genetic information, family
24 medical history, and authorizations concerning genetic tests or information is confidential in the

1 employment context. The category of genetic information includes information about use of
2 genetic services.

3
4 *Subsection (b) Retention of genetic information or family medical history.* If an
5 employer obtains any genetic information or family medical history under Section 202, it needs
6 the employee's authorization under Section 104 to retain the information. The separate storage
7 requirement serves to protect the employee's privacy and is modeled on La. Rev. Stat. §
8 23:368(B).

9
10 Under Section 105, an employee may revoke this authorization at any time. An open
11 drafting issue is whether an employee's revocation should be effective for future records only.
12 An employer may need to retain records if there is an ongoing dispute with the employee.

13
14 *Subsection (c) Retention of employee authorizations.* An employee's authorizations for
15 genetic testing and employer access, retention, or disclosure of genetic information are also
16 confidential records that must be kept separate from the employee's personnel files. Section 106
17 requires authorizations to be retained for six years from the date of the authorization or from the
18 last date it was in effect, whichever is later.

19
20 *Subsection (d) Disclosure of genetic information or family medical history.* The draft is
21 consistent with disclosure provisions in a number of states that have enacted (1) general privacy
22 protections for genetic information that prohibit disclosure without informed consent or
23 authorization (Alaska, Cal, Del, Fla, Maine, Mass, Nev, NH, NJ, NMex, NY, OR) or (2) specific
24 protections against the disclosure of genetic information by employers (Ariz, Fla, LA, Mass,
25 NH, NJ, Or, RI).

26
27 *Subsection (e) Genetic monitoring program.* An employer may retain and disclose
28 genetic information without an employee's specific authorization for a genetic monitoring
29 program. An employer is allowed access to this information only in an aggregate form that does
30 not identify individual employees, which should minimize the effects of retaining monitoring
31 information for an employee's privacy. An employer may need to disclose aggregate monitoring
32 information in order to analyze trends or take action to reduce risk in the workplace.

33 34 **SECTION 207. REMEDIES; LIMITATION OF ACTIONS.**

35 (a) An individual aggrieved by an alleged violation of this [article] may file a civil action
36 not later than two years after the individual discovers the alleged violation or a person exercising
37 reasonable care should have discovered the alleged violation. If the court finds a violation of
38 this [article], it may award relief including compensatory damages, back pay, front pay,

1 reassignment, reinstatement, injunctive relief, punitive damages, or other legal or equitable
2 relief. The court shall award a prevailing plaintiff reasonable attorney's fees and costs unless
3 justice requires otherwise.

4 **Reporter's Notes**

5
6 The draft is intended to provide remedies for privacy violations, employment
7 determinations based on misuse of genetic information, or other harms. Privacy violations
8 involve access, retention, or disclosure of genetic information that does not comply with the Act.
9 Employment determinations could include failure to license, hire, refer for employment,
10 promote, or termination, demotion, reduction in pay, reassignment, or any other adverse action.
11 Other harms could include torts such as intentional infliction of emotional distress. The
12 appropriate remedy will vary with the type of violation.
13

14 A privacy rights perspective assumes an intrinsic harm from the invasion of privacy,
15 whether or not consequential damages are incurred. Because of difficulties in measuring damage
16 to privacy interests, several states that provide a private right of action for privacy violations
17 involving genetic information also specify statutory damages, with higher amounts when the
18 violation is willful or leads to monetary gain for the violator. Alaska Stat. § 18.13.020 (actual
19 damages plus \$5,000, or plus \$1,000 if there is monetary gain); N.H. Rev. Stat. § 141-H:6 (not
20 less than \$1,000 per violation); NM Stat. Ann. § 24-21-6 (economic loss plus damages of up to
21 \$5,000 if the violation results from willful or grossly negligent conduct).
22

23 States with genetic statutes tend to provide relief for violations using a mixture of
24 administrative and civil processes, although a few have enacted criminal penalties. Many state
25 statutes that emphasize discrimination require employees to submit claims of unlawful
26 employment discrimination based on use of genetic information to a state agency or the federal
27 Equal Opportunity Employment Commission. Using a state employment discrimination agency
28 may make sense for enforcement of provisions related to employment decisions because such
29 agencies already have the apparatus in place to enforce state civil rights and disability statutes.
30 For privacy violations, however, such agencies do not have expertise in controlling the flow of
31 information and the typical remedies for employment discrimination are not necessarily
32 appropriate for a privacy violation. Enforcement could be turned over to an agency with that
33 expertise, but the drafters wish to avoid the cost of creating and funding a new agency.
34

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

1 **ARTICLE 3**

2 **HEALTH INSURANCE**

3 **SECTION 301. ACCESS TO GENETIC INFORMATION FOR HEALTH**
4 **INSURANCE.**

5 (a) In determining eligibility for health-insurance coverage and in setting rates, terms,
6 and conditions for a health-insurance policy, a health insurer may not:

7 (1) require or request an insured or an insured's family member to take a genetic
8 test;

9 (2) require or request an insured's genetic information or family medical history;
10 or

11 (3) inquire whether an insured or an insured's family member has taken or
12 refused to take a genetic test or accessed genetic services.

13 (b) Except as otherwise provided by law, a health insurer that receives a claim for
14 payment under a health-insurance policy may access, without specific authorization by the
15 insured, genetic information and family medical history that the health insurer may use under
16 Section 303 to determine a payment obligation.

17 (c) A health insurer that provides health-care services may provide a genetic test or
18 access genetic information or family medical history to the extent necessary to provide
19 therapeutic services for the insured.

20 **Reporter's Notes**

21
22 *Applicability of Article 3.* The draft is meant to apply broadly to health insurance,
23 whether issued on an individual, group, or other basis. This article closes the gaps left by Title I
24 of HIPAA, which prohibits discrimination in enrollment and premiums based on health status
25 related factors, including genetic information. Title I, however, does not apply to small group

1 and individual coverage, which is covered by this article. In addition to individual and group
2 health insurance policies, some state statutes reference health insurance issued on a franchise or
3 blanket basis. These forms of health insurance are also subject to this article.
4

5 The drafting committee intends that this article also applies to employee welfare plans
6 unless there is a controlling judicial decision that the article is preempted by the Employee
7 Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 et seq. Federal preemption
8 is relevant because the United States Supreme Court has held that ERISA applies to employee
9 benefit plans such as health insurance as well as to employee pension plans. *Inter-Modal Rail*
10 *Employees Ass'n v. Atchison, Topeka and Santa Fe Ry. Co.*, 520 U.S. 510 (1997). The United
11 States Supreme Court has recognized three types of preemption under ERISA that are relevant to
12 this draft act: express, complete, and conflict preemption.
13

14 In order to simplify the administration of plans by ensuring that they are subject to only
15 one set of regulations, ERISA expressly preempts state regulation of the administration of
16 employee benefit plans to the extent those regulations “relate to” employee benefit plans. 29
17 U.S.C. § 1144(a). The statute contains a savings clause, however, that saves laws that regulate
18 insurance from ERISA preemption. 29 U.S.C. § 1144(b)(2)(A). The issue of whether state
19 regulations are preempted by ERISA has led to extensive litigation.
20

21 Recently, the United States Supreme Court clarified the application of the savings clause.
22 In order to fall under ERISA’s savings clause, a state law must first be “specifically directed
23 toward” the insurance industry. *Kentucky Ass'n of Health Plans, Inc. v. Miller*, 123 S. Ct. 1471,
24 1475 (2003). Laws of general application that merely have “some bearing on insurers” do not
25 fall under the clause. *Id.* Second, the ERISA provision saves state laws that regulate
26 “insurance,” not “insurers,” so a law must regulate insurers “with respect to their insurance
27 practices.” *Id.* A state law regulates an insurer with respect to insurance practices if it controls
28 the terms of insurance policies, *id.* at 1476, or if it “substantially affect[s] the risk pooling
29 arrangement between the insurer and the insured,” *id.* at 1477.
30

31 The preemption question is further complicated by that fact that ERISA also contains
32 what is referred to as the “deemer clause,” which creates an exception to the savings clause. It
33 provides that “neither an employee benefit plan . . . nor any trust established under such plan,
34 shall be deemed to be an insurance company or other insurer . . . for purposes of any law of any
35 State purporting to regulate insurance companies . . .” 29 U.S.C. § 1144(b)(2)(B). The United
36 States Supreme Court has interpreted the deemer clause to exempt self-funded (i.e. uninsured)
37 health plans from the savings clause. Thus the Court concluded that “self-funded ERISA plans
38 are exempt from state regulation insofar as that regulation ‘relate[s] to’ the plans.” *FMC Corp.*
39 *v. Holliday*, 498 U.S. 52, 61 (1990).
40

41 The distinction in *FMC Corp.* between insured and self-insured health plans has not been
42 overruled and continues to be applied by lower courts. *See, e.g., Daly v. Marriott International,*
43 *Inc.*, 415 F.3d 889 (8th Cir. 2005) (“deemer clause” of ERISA preemption provision exempted

1 employer funded health plan from application of state mental-health parity law); *Blue Cross Blue*
2 *Shield of Alabama v. Sanders*, 138 F.3d 1347 (11th Cir. 1998).

3
4 The second type of ERISA preemption may affect the draft’s enforcement provisions.
5 “Complete preemption” occurs when Congress has “so completely [preempted] a particular area
6 that any civil complaint raising this select group of claims is necessarily federal in character.”
7 *Metropolitan Life Ins. Corp. v. Taylor*, 481 U.S. 58, 63-64 (1987). In *Taylor*, the United States
8 Supreme Court held that the civil enforcement provision of ERISA, 29 U.S.C. § 1132(a),
9 completely preempts common law breach of contract and tort claims for wrongful termination of
10 disability benefits. *See also Prudential Ins. Co. of Amer. v. Nat’l Park Med. Center, Inc.*, 413
11 F.3d 897 (8th Cir. 2005) (with respect to suits that could be brought under ERISA, civil
12 enforcement provision preempts Arkansas Patient Protection Act civil penalties).

13
14 A third type of preemption, “conflict preemption,” comes into play with civil remedies.
15 The United States Supreme Court has held that Congress intended to make the ERISA civil
16 enforcement remedy exclusive and that therefore a state-law cause of action that “duplicates,
17 supplements, or supplants” the ERISA civil remedy conflicts with congressional intent. *Aetna*
18 *Health, Inc. v. Davila*, 452 U.S. 200, 208 (2004) (Texas statute that created a cause of action
19 against HMOs for failure to exercise ordinary care in handling coverage decisions preempted).
20 *See also Hawaii Management Alliance v. Ins. Comm’n*, 100 P.3d 952 (Haw. 2004) (statute
21 providing attorney’s fees and costs for external review of insurer’s denial of coverage preempted
22 by conflict with ERISA).

23
24 *Access to Genetic Information.* This section limits the ability of health insurers to access
25 genetic information and family medical history consistent with the uses prohibited in Section
26 302 and permitted in Section 303.

27
28 *Subsection (a) Coverage decisions.* This subsection prohibits a health insurer from
29 requiring genetic tests or obtaining genetic information for uses associated with the issuance of
30 insurance. The draft prohibits those uses in Section 302.

31
32 *Subsection (b) Claims processing.* This subsection allows health insurers to access
33 genetic information for use in determining an insured’s payment obligations, as permitted in
34 Section 303. The exception for other legal requirements is included to avoid conflict with
35 HIPAA regulations on using and disclosing medical information for payment operations.

36
37 *Subsection (c) Medical treatment.* For health insurers such as HMOs, which also
38 provide health care services, access to genetic information for functions that involve determining
39 eligibility and terms of insurance need to be separated from access for health care provider
40 functions. These insurers may provide genetic tests to patients or access genetic information or
41 family medical history for therapeutic purposes as part of the practice of medicine, but not as
42 part of determining eligibility for insurance or for underwriting. Specific conditions for access
43 to genetic information for diagnosis or treatment are not covered by this draft because those uses
44 constitute the practice of medicine.

1

2 **SECTION 302. MISUSE OF GENETIC INFORMATION FOR HEALTH**

3 **INSURANCE.** A health insurer may not consider an insured’s genetic information or family
4 medical history in determining eligibility for health-insurance coverage or in setting rates, terms,
5 and conditions for a health-insurance policy.

6 **Reporter’s Notes**

7

8 This section reflects and combines the approaches of many states that prohibit the use of
9 genetic information for setting eligibility requirements and for underwriting in health insurance.
10 It partially closes the gaps left by HIPAA in that it extends beyond merely prohibiting complete
11 denial of coverage; the section also prohibits use of genetic information in determining rates
12 terms and conditions.

13

14 A determination of eligibility for coverage is meant to include decisions made in
15 connection with the offer, sale, continuation, or renewal of a health insurance policy. A
16 determination of rates, terms, and conditions includes establishing premiums, limiting coverage,
17 limiting or conditioning benefits, or making any other underwriting decisions. The prohibition
18 on using genetic information for these purposes also precludes an insurer from treating a
19 predisposing genetic characteristic as a preexisting condition for purposes of limiting or
20 excluding benefits or coverage. This is consistent with statutes in several states that do not
21 permit health insurers to impose preexisting condition exclusions based on predictive genetic
22 information in the absence of a diagnosis based on symptoms of the disease or condition.
23 (Alaska, Conn, Idaho, Iowa, Ky, OR).

24

25 There are many alternative approaches to regulating the use of genetic information in
26 health insurance. Some other states take an approach like that of HIPAA and use a non-
27 discrimination provision that prohibits higher premiums than those charged to similarly situated
28 individuals. (Alaska, Ark, Ill, Iowa). Yet other states prohibit the use of genetic information for
29 underwriting health insurance without actuarial justification. (Ariz, WV). In some states, use
30 of genetic information for risk selection is permitted if an individual submits the information
31 voluntarily or if the information is favorable to the individual. (Ill, Ind, Mass, Mo, NY). Yet
32 other states regulate this use by prohibiting insurers from increasing policy rates based on
33 genetic information. (Md, Mont, Or, Tex).

34

35 This section illustrates some of the problems with treating genetic information as a
36 distinct category of medical information. First, the section offers less protection than HIPAA in
37 terms of eligibility decisions for individual and small group coverage because it regulates use of
38 genetic information only, not information on all medical conditions. Second, it is often
39 permissible for insurers to consider existing medical conditions in determining coverage and

1 premiums under other law so long as they treat like situations alike. This section would impose
2 a different standard by prohibiting consideration of conditions revealed by a genetic test, thus
3 raising the practical question of which conditions are “genetic.” Even conditions with a genetic
4 component are rarely entirely “genetic.”
5

6 A major policy question for the drafting committee is whether health care insurers should
7 be prohibited from denying coverage or offering less favorable terms based on an applicant’s
8 manifest genetic disease or only on an applicant’s predisposing genetic characteristics. An
9 argument can be made that protection for genetic information as defined in this draft is too wide.
10 As discussed above, the prohibition would create a different standard for genetic illnesses than
11 for other medical conditions. Some analysts maintain that attempts to prevent genetic
12 discrimination are mostly meaningless without protection for people who have genetic diseases.
13 See Mark A. Rothstein, *Genetic Privacy and Confidentiality: Why They are so Hard to Protect*,
14 26 J. L. Med. & Ethics 181 (1998). Others think that this would place too great a burden on
15 insurers. See, e.g., Henry T. Greely, *Genotype Discrimination: The Complex Case for Some*
16 *Legislative Protection*, 149 U. Pa. L. Rev. 1483, 1503 (2001). An alternative consistent with the
17 latter position would be to limit the restrictions to predictive information by substituting
18 “predisposing genetic characteristic” for “genetic information” in subsection (a).
19

20 SECTION 303. USE OF GENETIC INFORMATION FOR HEALTH

21 INSURANCE.

22 (a) A health insurer that receives a claim for payment under a health-insurance policy
23 may determine a payment obligation using:

24 (1) genetic information and family medical history regarding the need for a
25 genetic test, but not the results of the test, if genetic testing or genetic counseling is the service
26 for which the claim is made; or

27 (2) the portion of genetic information or family medical history necessary to
28 determine the insurer’s obligation to pay for health-care services when the reason for rendering
29 the services is a genetic condition or predisposing genetic characteristic.

30 (b) A health insurer that provides health-care services may use an insured’s genetic
31 information or family medical history for therapeutic purposes for the insured.

1 **Reporter's Notes**

2
3 *Subsection (a) Payment obligations.* This subsection highlights the potential role for
4 genetic information in providing payment for genetic tests and health care services. First,
5 genetic information such as family history may be necessary for preauthorization for a genetic
6 test or service or for approval of payment for a genetic test or service. Second, health care
7 services may be medically justified by a predisposing genetic characteristic or a genetic
8 condition. In this context, genetic “condition” should be interpreted broadly to include the full
9 range of health effects influenced by a genotype, including a disease or disorder.

10
11 This subsection is modeled on a Utah provision.

12
13 *Subsection (b) Health-care services.* Health insurers such as HMOs, which also provide
14 health care services, need to be able to use genetic information in order to function as health care
15 providers. These insurers may use genetic information or family medical history for therapeutic
16 purposes as part of the practice of medicine, but not as part of determining eligibility for
17 insurance or for underwriting. Specific conditions for use of genetic information for diagnosis or
18 treatment are not covered by this draft because those uses constitute the practice of medicine.
19

20 **SECTION 304. RETENTION OF GENETIC INFORMATION FOR HEALTH**

21 **INSURANCE.** A health insurer that retains genetic information or family medical history shall
22 comply with the terms of the regulations that govern Security Standards for the Protection of
23 Electronic Protected Health Information pursuant to the Health Insurance Portability and
24 Accountability Act of 1996, 45 C.F.R. Part 164 Subpart C, as if the insurer were covered by that
25 Act.

26 **Reporter's Notes**

27
28 This section extends the protections of HIPAA to all genetic information retained by
29 health insurers, whether covered by HIPAA or not. The health insurers that are not covered by
30 HIPAA's Privacy Rule but would be brought under it by this provision are primarily small
31 employer-sponsored group health plans (less than 50 participants) or employer-sponsored group
32 health plans that are administered solely by the employer that established and maintains the plan.
33 See 45 C.F.R. § 160.202. The drafting committee noted that it would consider deleting this
34 section.
35

1 **SECTION 305. DISCLOSURE OF GENETIC INFORMATION BY HEALTH**

2 **INSURERS.** A health insurer may disclose an insured’s genetic information to a person other
3 than the insured if the health insurer has obtained the insured’s authorization.

4 **Reporter’s Notes**

5
6 This section conditions the disclosure of an insured’s genetic information on the
7 authorization of the insured. In some jurisdictions, however, health care providers may have a
8 common-law duty to inform others of a genetic disorder. This case law may require disclosure
9 by a health insurer without the insured’s consent.

10
11 New Jersey’s court has recognized a physician’s duty to warn those “known to be at risk
12 of avoidable harm from a genetically transmissible condition.” *Safer v. Pack*, 677 A.2d 1188
13 (N.J. Super. Ct. App. Div. 1996). The defendant in the case was the physician who had treated
14 the plaintiff’s father for colorectal cancer that led to the father’s death when the plaintiff was a
15 child. The plaintiff inherited multiple polyposis, an inherited condition that if undiscovered and
16 untreated, leads to metastatic colorectal cancer. The court found a duty to “take reasonable
17 steps” to warn that “extends beyond the patient to members of the immediate family of the
18 patient who may be adversely affected by a breach of that duty.” It noted, but did not determine,
19 the issue that would arise if the father had instructed the doctor not to disclose details of the
20 illness or the genetic risk. In that event, it would be necessary to resolve the conflict between
21 physician-patient confidentiality and the duty to warn.

22
23 Minnesota has also recognized a duty regarding genetic testing and diagnosis that reaches
24 beyond the patient. The plaintiff alleged that her daughter’s physicians were negligent in failing
25 to diagnose a genetic disorder in the daughter that led the mother to conceive another child with
26 the same genetic disorder. *Molloy v. Meier*, 679 N.W.2d 711 (Minn. 2004). The court noted that
27 genetic testing and diagnosis affect not only the patient, but can benefit or harm both the patient
28 and her family. The Fragile X disorder is one that physicians ordinarily report to parents and it
29 was foreseeable that a negligent diagnosis of the disorder would cause harm to the family as well
30 as the patient. The court held that the duty to warn extends to “biological parents who
31 foreseeably may be harmed by a breach of that duty.” It did not consider whether it should
32 extend to additional family members.

33
34 The Florida Supreme Court has similarly held there is a duty to warn of the likelihood
35 that a condition was inherited by a patient’s children but, in contrast to the Minnesota and New
36 Jersey courts, it found that the duty is satisfied by warning the patient. *Pate v. Threlkel*, 661
37 So.2d 278 (Fla. 1995). The court observed that a patient can normally be relied upon to pass on
38 the warning and emphasized the heavy burden that would be entailed in seeking out and warning
39 family members.

40
41 Requirements for an authorization to disclose are contained in Section 104.

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SECTION 306. REMEDIES; ENFORCEMENT; LIMITATION OF ACTIONS.

(a) An individual aggrieved by an alleged violation of this [article] may file a civil action not later than two years after the individual discovers the alleged violation of this [article] or a person exercising reasonable care should have discovered the alleged violation of this [article].

(b) A violation of this [article] is a violation of [the state unfair practices insurance law]. An individual aggrieved by an alleged violation of this [article] may seek enforcement by the [state commissioner of insurance] not later than two years after the individual discovers the alleged violation of this [article] or a person exercising reasonable care should have discovered the alleged violation of this [article].

(c) If a court that finds a violation of this [article], it may award compensatory damages, injunctive relief, including expungement of records, or any other appropriate remedy. The court shall award a prevailing plaintiff reasonable attorneys fees and costs unless justice requires otherwise.

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

Reporter’s Notes

Many state statutes that prohibit discrimination in health insurance based on genetic testing or information declare that a violation is an unfair and deceptive insurance act or practice under the state insurance code. They often provide that the State Commissioner of Insurance shall enforce the prohibitions.

This draft concerns privacy as well as discrimination or misuse of genetic information in insurance. It provides a private right of action for an aggrieved individual. Alternatively, an aggrieved individual may seek enforcement through the State Commissioner of Insurance.

1 As in the case of the remedies for privacy violations in the employment context, the
2 drafting committee may want to consider whether statutory damages would be appropriate for a
3 violation of privacy interests.

1 **ARTICLE 4**

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

3 **SECTION 401. GENETIC TESTING SUPPLIED FOR LIFE, DISABILITY-**
4 **INCOME, AND LONG-TERM-CARE INSURANCE.**

5 (a) If a genetic test is approved as provided in Section 404, an insurer may request or
6 require an insured or an insured's family member to take the genetic test in connection with the
7 provision of life, disability-income, or long-term-care insurance and, with prior authorization of
8 the insured that meets the requirements of Section 104, may supply the test to the insured.

9 (b) An insurer that supplies a genetic test to an insured in connection with the provision
10 of life, disability-income, or long-term-care insurance shall:

11 (1) inform the insured that the insured should obtain genetic counseling about the
12 risks and benefits of a genetic test before authorizing the test and about the test result;

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

16 (3) require that the insured's biological sample obtained for a genetic test be
17 destroyed as soon as permitted by law following the completion of the test unless the insured
18 authorizes retention of the sample or unless otherwise ordered by a court, arbitral tribunal, or
19 administrative agency.

20 **Reporter's Notes**

21
22 *Applicability of Article 4.* This article applies to life insurance, disability-income
23 insurance, and long-term-care insurance issued on an individual, group, or other basis. Including
24 individual policies is significant because individual insurance policies are subject to
25 underwriting and many life, disability-income, or long-term-care insurance policies are issued on

1 an individual basis. The draft does not distinguish between individual and group insurance,
2 however, because most of the states that regulate genetic testing or the use of genetic information
3 for issuing life, disability-income, or long-term-care insurance treat both individual and group
4 insurance identically.

5
6 The justification for including life, disability-income, and long-term-care insurance in a
7 separate article from health insurance is that these insurance policies tend to be viewed as
8 financial products that are less necessary than health insurance. That, however, is a contested
9 view. Life insurance plays a central role in the financial lives of many individuals and families.
10 Disability-income and long-term-care insurance are increasingly viewed as a necessary adjunct
11 to health insurance and many states regulate disability-income and long-term-care insurance as
12 health insurance.

13
14 There are differences in underwriting principles among the three types of insurance. Life
15 insurance underwriting is concerned with mortality and uses life expectancy tables. In contrast,
16 disability-income underwriting is concerned with morbidity and long-term-care underwriting is a
17 hybrid process. These differences do not seem to require different treatment in terms of genetic
18 information.

19
20 *Genetic testing and information.* This section and the following one limit access to
21 genetic information by insurers that provide life, disability-income, or long-term-care insurance.
22 This section limits genetic testing and the following section limits access to genetic information
23 in general. The limitations are based on the philosophy that insurers may continue current
24 information gathering practices, but may not expand their collection of genetic information
25 unless and until there is a strong scientific basis for its use to predict mortality and morbidity. It
26 is the drafting committee's understanding that life, disability-income and long-term-care insurers
27 do not at present require applicants to take genetic tests, but do collect family history information
28 for use in determining eligibility and in underwriting.

29
30 The drafting committee considered, but did not adopt, an approach to regulating genetic
31 information for life, disability-income or long-term-care insurance based on the amount of the
32 insurance policy. The suggestion was to prohibit genetic testing and consideration of genetic
33 information for policies worth less than a specified monetary threshold. Above that value,
34 insurers would be permitted to consider genetic information freely.

35
36 The arguments for restricting access to genetic information by the insurance industry are
37 that this information is particularly private and its predictive power is easily exaggerated. There
38 are privacy concerns with commercial access to sensitive genetic information and predictions
39 that individuals will avoid genetic testing for fear of adverse effects on their insurability. There
40 is also a possibility that insurers may require applicants to take genetic tests and then deny
41 insurance or charge more based on genetic characteristics, unfairly making coverage unavailable
42 to people who are not sick from the genetic condition and never will become sick from that
43 condition. From the industry perspective, as with health insurance, insurers worry about adverse
44 selection. If applicants seek coverage because a genetic characteristic exposes them to risk, but

1 the insurer does not have this information, this puts the insurer at a financial disadvantage. *See*
2 *generally* Mark A. Rothstein, ed., *Genetics and Life Insurance: Medical Underwriting and Social*
3 *Policy* (2004).

4
5 A 1997 study by the Human Genetics Advisory Commission in the United Kingdom
6 concluded that it is unlikely that actuarially-sound genetic predictions of adult death will be
7 validated and available anytime in the near future. Genetic tests need to be connected to medical
8 and epidemiological research to establish what consequences for health and life-span can be
9 inferred from a given genetic test. The Commission concluded that a requirement to disclose
10 genetic tests as a condition of obtaining insurance would be acceptable only after research has
11 established an association between a given pattern of test results and life events that are relevant
12 for the insurance product. It recommended continuing a moratorium on requiring test results.
13 Human Genetics Advisory Commission, *The Implications of Genetic Testing for Insurance*
14 (1997).

15
16 *Genetic testing.* This section prohibits insurers from requiring applicants to have genetic
17 testing as a condition of obtaining life, disability-income or long-term-care insurance unless a
18 test has been certified as providing a relevant prediction. The section is consistent with the
19 moratorium recommended by the UK Human Genetics Advisory Commission because there is
20 no research establishing an association between a pattern of genetic test results and life events
21 relevant to insurance coverage.

22
23 The section is also consistent with genetic testing prohibitions in force in California,
24 Massachusetts, and Vermont, except that it allows the prohibition to be modified as justified by
25 scientific developments. Vermont and Massachusetts prohibit insurers from requiring applicants
26 to take a genetic test as a condition of obtaining or renewing a policy. California prohibits long-
27 term-care insurers from requiring genetic testing for use in determining insurability or in
28 underwriting. *See* Cal. Ins. Code § 10233.1 (long-term-care insurance); Mass. Gen. L. Ann. 175
29 § 120E (life insurance); Mass. Gen. L. Ann. 175 § 108I (disability and long-term-care
30 insurance); Vt. Stat. Ann. § 9334 (any insurance).

31
32 The section also sets forth requirements similar to those imposed on employers who
33 provide genetic tests, but does not require insurers to provide genetic counseling.

34
35 **SECTION 402. ACCESS TO GENETIC INFORMATION FOR LIFE,**
36 **DISABILITY-INCOME, AND LONG-TERM-CARE INSURANCE.**

37 (a) Unless genetic information is based on a genetic test that is approved as provided in
38 Section 404, an insurer may not knowingly obtain or directly or indirectly inquire about, request
39 or require an insured to provide an insured's genetic information in connection with the

1 provision of life, disability-income, or long-term-care insurance.

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

4 **Reporter’s Notes**

5
6 This section limits the extent to which an insurance company may access genetic
7 information or the results of genetic testing based on the rationale discussed in the reporter’s
8 notes to Section 401. Subsection (a) permits access to genetic information if it is based on a
9 genetic test that has been approved under Section 404. Otherwise access is prohibited. This
10 prohibition does not apply to family medical history, which is not included in the definition of
11 “genetic information.” Subsection (b), moreover, explicitly permits insurers to seek information
12 about family medical history, which they have traditionally used for underwriting.
13

14 **SECTION 403. MISUSE OF GENETIC INFORMATION FOR LIFE,**
15 **DISABILITY-INCOME, AND LONG-TERM-CARE INSURANCE.** Unless genetic
16 information is based on a genetic test that is approved as provided in Section 404, an insurer may
17 not use genetic information about an insured’s predisposing genetic characteristics to determine
18 eligibility or rates, terms, and conditions for life, disability-income or long-term-care insurance.

19 **Reporter’s Notes**

20
21 The determination of eligibility for coverage includes decisions made in connection with
22 the offer, sale, continuation, or renewal of an insurance policy. The determination of rates,
23 terms, and conditions includes establishing premiums, limiting coverage, limiting or
24 conditioning benefits, or making any other underwriting decisions.
25

26 This section prohibits the use of genetic information for determining eligibility or
27 underwriting of life, disability-income, and long-term-care insurance unless the genetic test has
28 been certified using the procedure in Section 404. Traditional insurance underwriting has been
29 based on medical histories and tests that indicate existing medical conditions. The draft permits
30 those practices to continue. Using predictions based on predisposing genetic characteristics that
31 have not been expressed as a disease or condition would be a new step, however, and there is a
32 great risk that such predictions would not be reliable in the context of insurance.
33

34 The section ties use of genetic information about predisposing characteristics to the
35 process in Section 404 for ensuring that the genetic test provides a reliable prediction of

1 individual mortality or morbidity. Otherwise, life, disability-income and long-term-care insurers
2 may not use genetic information about predisposing characteristics for determining eligibility or
3 in underwriting.
4

5 This prohibition is consistent with regulation in a number of states. Because genetic tests
6 are not yet routine in medical care and few individuals have previously taken genetic tests when
7 they apply for insurance, the prohibitions on requiring tests in California, Massachusetts, and
8 Vermont have the effect of preventing the use of genetic information. In addition, a number of
9 states directly prohibit insurers from using genetic information to determine eligibility or in
10 underwriting. *See* Colo. Rev. Stat. § 10-3-1104.7(3)(b) (group disability-income & long-term-
11 care); Kan. Stat. Ann. § 40-2259(d) (disability-income & long-term-care); Or. Rev. Stat. §
12 746.135 (genetic information from a blood relative for life, disability-income & long-term-care
13 insurance); Vt. Stat. Ann. tit. 18, § 9334(a) (same).
14

15 Unlike the draft's treatment of genetic information in employment or health insurance,
16 the restriction on use of genetic information in life, disability-income & long-term-care
17 insurance is narrower in that it applies only to predisposing genetic characteristics. Therefore,
18 insurers are not restricted from using genetic information with regard to a medical condition that
19 has been diagnosed. The scope is similar to Arizona's statute, which permits disability-income
20 and long-term-care insurers to use genetic information only if there is an actual diagnosis of a
21 genetic condition. Ariz. Rev. Stat. Ann. § 20-448(F).
22

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

34 With the draft's narrow definition of "genetic information," an insurer would be able to
35 use genetic data revealed by an individual's family medical history to determine eligibility or to
36 underwrite without restriction. One member of the subcommittee raised the question of whether
37 there should be any limits on insurers' use of family medical history. The question was
38 motivated by a concern that even if disclosures to insurers do not change, insurers may be able to
39 do more with those disclosures using ever more sophisticated computer technology. The
40 drafting committee may want to consider whether it is desirable to prevent new uses of family
41 history information that may become possible and if so, what limits would be appropriate.
42

43 ALTERNATIVES FOR DRAFTING COMMITTEE CONSIDERATION

1 **Alternative A – Administrative Approval of Genetic Tests**

2 **SECTION 404. USE OF GENETIC INFORMATION FOR LIFE, DISABILITY-**
3 **INCOME, AND LONG-TERM-CARE INSURANCE.** Unless the [State Commissioner of
4 Insurance] determines, in consultation with the [State Department of Public Health], that
5 research has established that genetic information reliably relates to an insured’s mortality, the
6 use of a genetic information about an insured’s predisposing genetic characteristics to determine
7 eligibility and rates, terms, and conditions for life insurance is unfair discrimination in violation
8 of [state unfair practices insurance law] . An insurer may petition for a determination under this
9 subsection and the [Commissioner], in consultation with the [State Department of Public
10 Health], may issue an advisory opinion on whether a genetic test or pattern of test results
11 provides reliable information relating to an individual’s mortality, based on sound actuarial
12 principles or actual or reasonably anticipated claim experience. An insurer may petition for a
13 new hearing to update the advisory opinion after two years from the date of the opinion.

14 *Legislative Note: States should insert for [State Commissioner of Insurance] and [State*
15 *Department of Public Health] the appropriate titles of these departments. [State unfair*
16 *practices insurance law] should be replaced with the title of the relevant statute.*
17

18 **Alternative B – Geneticist or Genetic Counselor Approval of Genetic Tests**

19 **SECTION 404. USE OF GENETIC INFORMATION FOR LIFE, DISABILITY-**
20 **INCOME, AND LONG-TERM-CARE INSURANCE.** Unless a geneticist or genetic
21 counselor determines that a positive genetic test or pattern of test results is reliably associated
22 with an increased medical risk of mortality and certifies the magnitude of the increase in risk, the
23 use of a genetic information about an insured’s predisposing genetic characteristics to determine

1 eligibility or rates, terms, or conditions for life insurance is unfair discrimination in violation of
2 [State unfair practices insurance law].

3 **Legislative Note:** *[State unfair practices insurance law] should be replaced with the title of the*
4 *relevant statute.*

5
6 **End of Alternatives**

7
8 **Reporter's Notes**

9
10 The insurance subcommittee offers two alternatives to provide assurances that insurance
11 companies that are permitted to use genetic information, but not misuse it. Both alternatives are
12 designed to protect against the premature or improper use of predictions based on genetic
13 information. The risk of misuse is increasing because of the explosion of genetic tests available,
14 the general lack of governmental oversight for these tests, and common misperceptions about the
15 extent to which a genetic test can predict a future medical disease or condition. In addition, the
16 pathways for gene expression remain uncertain. Links between most genetic characteristics and
17 the incidence of disease are extremely complex and depend on the interrelation of many factors,
18 both genetic and environmental.

19
20 Even with draft's restrictions on genetic testing by insurance companies, access to
21 genetic information in medical records will increase. More than 1,000 genetic tests are available
22 clinically as of early 2007; hundreds more are available to researchers. Some are marketed
23 directly to consumers with claims that they can be used to individually customize vitamins and
24 diet as well as test for disease. There is no government oversight of the validity of the tests used
25 for research or available through medical professionals.

26
27 The insurance industry has expressed a view that it must be able to develop its use of
28 genetic information along with the rapid development of knowledge in the genetic field. Both
29 alternatives provide a mechanism that will allow use of genetic information to evolve in response
30 to new scientific information that may justify the use of genetic information for eligibility and
31 underwriting determinations.

32
33 Alternative A provides a means for regulatory oversight of the use of genetic information
34 by insurers. Rather than allowing insurers to use genetic information subject to a challenge that
35 this use constitutes an unfair practice, Alternative A requires a threshold finding that there is a
36 reliable relationship between a predisposing genetic characteristic and the incidence of mortality.
37 It places the responsibility for assessment of scientific information about genetic risks on state
38 insurance regulators, but acknowledges their need for additional expertise by stipulating that
39 they must consult with experts in the department of public health. The process would allow an
40 insurer's use of genetic information to change as research develops reliable connections between
41 genetic characteristics and risk of mortality by permitting insurers to petition state regulators for

1 a determination or a new determination when they believe that use of genetic information can be
2 justified.

3
4 An independent scientific advisory board in the United Kingdom that similarly analyzed
5 the actuarial significance of genetic tests found that only the test for Huntington Disease
6 qualified to provide a reliable prediction.

7
8 Alternative B leaves the determination that there is a reliable relationship between
9 genetic information and mortality to the insurance companies. A check is provided through the
10 requirement that a geneticist or genetic counselor must be involved in the process. This expert
11 would not make actuarial determinations, but would evaluate the medical literature to determine
12 the accuracy and completeness of the data an actuary proposes to use and the reliability of the
13 prediction possible with the genetic information.
14

15 **SECTION 405. RETENTION OF GENETIC INFORMATION FOR LIFE,**
16 **DISABILITY-INCOME, AND LONG-TERM-CARE INSURANCE.**

17 (a) A life, disability-income, or long-term-care insurer may retain a record of an
18 insured's authorization for the insurer to obtain, retain, or disclose genetic information.

19 (b) An insured's genetic information is a confidential medical record that a life,
20 disability-income, or long-term-care insurer may retain only with prior authorization of the
21 insured.

22 **Reporter's Notes**
23

24 This section permits insurers to retain genetic information under certain circumstances.
25 It follows the practice of the states with statutes that require authorization or informed consent
26 for the retention of genetic information and do not treat life, disability-income, or long-term-care
27 insurers differently than others who might retain such information. Other states, however,
28 exempt these insurers from their requirements for authorization or informed consent. (E.g.,
29 Mass., Nev., NH, NMex, Ok)
30

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

1
2 **SECTION 406. DISCLOSURE OF GENETIC INFORMATION IN LIFE,**
3 **DISABILITY-INCOME, AND LONG-TERM-CARE INSURANCE.**

4 (a) A life, disability, or long-term-care insurer may disclose an insured's genetic
5 information if the insurer has obtained the insured's prior authorization for the disclosure.

6 (b) An insured, upon request, may inspect and obtain a copy of genetic information from
7 the life, disability, or long-term-care insurer's files on the insured.

8 (c) If an insurer uses an insured's genetic information to make an adverse determination
9 regarding eligibility or rates, terms, or conditions for life insurance, the insurer shall provide
10 notice to the insured. The insured may choose to repeat a genetic test to verify the analysis used
11 in the adverse determination. If the first analysis is found to be inaccurate, the insurer shall
12 reconsider the adverse determination.

13 **Reporter's Notes**

14 *Subsection (a).* This subsection is drafted to allow the committee to consider whether the
15 ability of life, disability-income, and long-term-care insurers to disclose genetic information
16 should be restricted. The insurance industry argues that a special disclosure provision for
17 genetic information is unnecessary because of the number of states that have adopted statutes
18 based on National Association of Insurance Commissioners' model laws dealing with general
19 privacy of information.
20

21
22 *Subsections (b) & (c).* Under these subsections, an insured is allowed to access his own
23 records and is provided an opportunity to correct mistakes in genetic information. The
24 subsections are modeled on Florida procedures which require the DNA analysis to be repeated in
25 the event of an adverse determination. Fla. Stat. § 760.40(3). Delaware also has a special
26 provision that allows an individual to access his genetic records and to correct those records. 16
27 Del. Code Ann. § 1223.
28

29 **SECTION 407. REMEDIES; ENFORCEMENT; LIMITATION OF ACTIONS.**

1 (a) An individual aggrieved by an alleged violation of this [article] may file a civil action
2 not later than two years after the individual discovers the alleged violation of this [article] or a
3 person exercising reasonable care should have discovered the alleged violation of this [article].

4 (b) A violation of this [article] is a violation of [the state unfair practices insurance law].
5 An individual aggrieved by an alleged violation of this [article] may seek enforcement by the
6 [state commissioner of insurance] not later than two years after the individual discovers the
7 alleged violation of this [article] or a person exercising reasonable care should have discovered
8 the alleged violation of this [article].

9 (c) If a court that finds a violation of this [article], it may award compensatory damages,
10 injunctive relief, including expungement of records, or any other appropriate remedy. The court
11 shall award a prevailing plaintiff reasonable attorneys fees and costs unless justice requires
12 otherwise.

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

16
17 **Reporter's Notes**

18
19 This section follows the enforcement provision for health insurance.

1 **ARTICLE 5**

2 **MISCELLANEOUS PROVISIONS**

3 **SECTION 501. 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 502. 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 503. EFFECTIVE DATE.** This [act] takes effect