

# State Legislative Efforts to Regulate Use and Potential Misuse of Genetic Information

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## Summary

The purpose of this study was to review existing and proposed legislation specifically intended to regulate the collection, use, and potential misuse of genetic data. The study encompasses laws relating to confidentiality, informed consent, discrimination, and related issues. It excludes from consideration legislation relating to medical records generally that may bear indirectly on genetic information. It also excludes both legislation relating to the regulation of DNA data collection for law enforcement purposes and state laws relating to the confidentiality of data collected by newborn-screening programs. While relatively few laws that explicitly regulate the treatment of genetic information have been enacted to date, a considerable amount of activity is currently underway in the nation's legislatures. Although most of the bills under consideration are not comprehensive in scope, they reflect a growing societal awareness that the uncontrolled dissemination and use of genetic data entails significant risks.

## Introduction

No act is more fundamental to the articulation of a public policy than is the enactment of legislation. It is a relatively easy task to identify and track bills—such as the Human Genome Privacy Act introduced in the United States House of Representatives last year and now pending before the House Committee on Government Operations (Human Genome Privacy Act 1991)—that propose to regulate the use or potential misuse of genetic information at the federal level. Given the power of the federal government, it is tempting to conclude that observation at this level will accurately reveal the views of the general public on issues relating to genetic data. This, however, is naive. Fifty-one legislatures work simultaneously in this country, and state legislatures often act on particular subjects either without or in advance of federal action. State legislative trends may stimulate federal lawmaking or redi-

rect policy. A careful assessment of existing and proposed laws—particularly in an area such as genetics, where complex technological issues are involved—assists policymakers in improving the regulatory process.

Laws that are formally enacted by state legislatures and signed by the governors represent only a tiny fraction of the total number of bills introduced each year. Thus, examination of bills considered but not yet adopted can help to identify important trends. Indeed, at the level of public policy, one way to measure the rise of an issue is to monitor the level of attention it is receiving from legislators who introduce or sponsor bills, regardless of whether such bills ever become law. It is against this backdrop, and to identify elements for inclusion in “model” legislation, that this study was conducted.

## Material and Methods

Using statutory and bill-tracking data bases available on the computer-assisted legal research tools LEXIS and WESTLAW, coupled with traditional manual legal research methods, we identified all existing state statutes and recently introduced bills that explicitly address issues of confidentiality, informed consent, discrimination, or related matters in the con-

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text of genetic information generally. We then analyzed the content of the full text of all materials located, narrowing the focus to an examination of legislation relevant to information generated in clinical (as opposed to forensic or other) contexts. Included in the final review were pertinent state statutes already enacted, legislation recently considered and rejected, and bills recently proposed that remain pending. We also examined relevant federal legislation—both existing and proposed.

## Results

The 50-state and federal survey identified a number of statutes that have been enacted and several new bills that have recently been enacted or proposed. These address chiefly the problems of maintaining the confidentiality of genetic information and/or ensuring informed consent in testing situations. Some legislation has also focused on regulating the use of genetic data once it reaches the hands of third parties—particularly, insurance companies and employers.

### *Legislation Relating to Confidentiality and Informed Consent*

A number of states have statutes in place that are intended to ensure informed consent in genetic testing and/or to protect the confidentiality of various types of genetic information. Some states have statutes that protect the confidentiality of genetic information about specific diseases (e.g., sickle cell anemia) in specific settings (Kan. Stat. Ann. 1978). Most confidentiality laws, however, are included within comprehensive statutory schemes generally designed to regulate the uses of birth defects registries or the practices of large-scale genetic screening programs, and most are not very specific (Md. Ann. Code I 1986). Some of the more recently enacted statutes of this type, however, do establish somewhat more detailed directives regarding the maintenance of confidentiality (Ct. Gen. Stat. Ann 1989).

Legislation considered but rejected last year in California (Calif. Senate Bill 1991) would have made explicit that no genetic testing (broadly defined as “any attempt to determine the presence of genetic factors in a person which may indicate a hereditary disorder”) could be performed on a person in that state without the person’s consent. It would also specifically have disallowed genetic testing of a child over the objection of the child’s parent or guardian who, in turn, would need to be both fully informed of the purpose of the testing and given a reasonable opportunity to oppose it.

The California bill would also have required that any genetic test result, as well as any personal information or specimen obtained in connection with performing a genetic test, be treated as a confidential medical record that could not be disseminated to third parties without the consent of the person tested (or, in the case of a child, the consent of a parent or guardian). For consent to the release of any such information to be valid, the person would have to have been fully informed of the scope of the information to be released, to whom the information would be released, the purposes of the release, and the associated risks and benefits. The California bill recognized only two types of genetic information that could be disclosed without satisfying these requirements: statistical data compiled without reference to the test subject’s identity and information released for research purposes where certain specified safeguards are satisfied. If this bill had become law, a person whose informed consent or confidentiality rights were violated would have been able to recover actual damages and a minimum of \$10,000 in civil damages, in addition to attorney’s fees and litigation costs.

A bill introduced last year in New York (N.Y. Senate Bill I 1991; N.Y. Assembly Bill I 1991) similarly would expressly make all records, findings, and results of genetic testing confidential and would prohibit their disclosure without the consent of the person to whom they relate. “Genetic testing” in the New York bill is defined as “medical and biological examination and analysis of a person to determine the presence and composition of genes in [that] person’s body”; it also specifically includes DNA profile analysis. The bill would make genetic information the exclusive property of the person it relates to, specifically forbidding its release to insurance companies, employers, or potential employers. The New York bill would, however, permit the disclosure to police officers or other law enforcement officials of genetic data relating to a person being criminally investigated or prosecuted. A second bill pending in New York would specifically provide for the confidentiality of all test results, medical records, and other information in connection with Tay-Sachs screening (N.Y. Senate Bill II 1991; N.Y. Assembly Bill II 1991).

In Wisconsin, comprehensive genetic testing legislation signed by the governor in early 1992 (Wisc. Act 1991) prohibits both insurers and employment-related entities from requiring or administering a genetic test without the test subject’s prior written and informed consent. The new Wisconsin law defines “genetic test-

ing” for these purposes as “a test of a person’s genes, gene products or chromosomes, for abnormalities or deficiencies, including carrier status, that are linked to physical or mental disorders or impairments, or that indicate a susceptibility to illness, disease, impairment or other disorders, whether physical or mental, or that demonstrate genetic or chromosomal damage due to environmental factors.” It also provides that “no person” can disclose to either an insurer or employment entity the fact that another person has taken a genetic test, or the results of that test, without the subject’s consent. Violations of these provisions are treated as misdemeanors under Wisconsin law.

#### *Legislation Relating to Discrimination in Insurance*

Several states have enacted or are considering legislation designed to regulate the use of genetic information by insurance companies or to prevent such information from reaching their hands in the first place. Currently, California has the most detailed statutory prohibition of insurance discrimination on the basis of genetic condition. First, the state has a general statutory policy against genetic discrimination, a policy that disallows “stigmatization” and “discrimination” against “carriers of most deleterious genes” (Calif. Health & Safety Code 1990). More specifically, all life or disability insurers in that state are prohibited from refusing to issue, sell, or renew policies; from setting discriminatory policy rates or premiums; from including discriminatory policy conditions or stipulations; and from discriminating in the fees or commissions of agents or brokers writing or reviewing policies “solely by reason of the fact that the person to be insured carries a gene which may, under some circumstances, be associated with disability in that person’s offspring, but which causes no adverse effects on the carrier” (Calif. Insurance Code I 1977). The law specifically mentions the traits for Tay-Sachs disease, sickle cell anemia, thalassemia, and hemophilia A but states that its proscriptions are not limited to discrimination against persons with those particular diseases. Nonprofit hospital service plans (Calif. Insurance Code II 1977), health-care-service plans (Calif. Health & Safety Code 1977), and self-insured employee welfare benefit plans (Calif. Insurance Code III 1977) operating in California are each subject to analogous statutory prohibitions which may be further broadened under new legislation introduced in 1992 (Calif. Assembly Bill 1992).

Legislation considered last year in California (Calif.

Senate Bill 1991) would have taken these prohibitions a step further by disallowing each of these same entities from requiring any person to undergo genetic testing as a condition of obtaining or renewing coverage. This legislation (part of the same bill discussed above dealing with informed consent and confidentiality) would have also flatly prohibited insurance discrimination against a person on the basis that the person “has or may have a hereditary disorder”—a seemingly much broader prohibition than that which exists under current California law. Violations of this law would have resulted in liability for both actual damages and at least \$10,000 in civil damages, as well as for attorney’s fees and costs.

A recently proposed, but now defeated, bill in Rhode Island (R.I. Gen. Assembly Bill 1990) would likewise have placed a broad-based prohibition on genetic discrimination in a wide variety of insurance contexts. This bill, which would have applied to insurers issuing accident and sickness insurance policies, nonprofit hospital service corporations, nonprofit medical service corporations, health maintenance organizations, and catastrophic health insurers, would have prohibited utilizing genetic test results to reject applicants, unless there was evidence that the applicant was currently ill from the disease for which the applicant was tested. The bill also would have barred terminating the coverage of a policyholder on the basis of a pre-existing medical condition, unless some evidence existed that the person was currently ill from the genetic disease in question.

Statutory provisions already in effect in Maryland take a similar, although a somewhat less expansive, approach. Maryland law prohibits both life and health insurers from permitting any differential in ratings, premium payments, or dividends solely because the applicant or insured carries the trait for sickle cell anemia, beta-thalassemia, hemoglobin C disease, or Tay-Sachs disease, “or any genetic trait which is harmless within itself,” unless there is “actuarial justification” for treating such persons differently (Md. Ann. Code II 1986).

Two states have enacted legislation that generally prohibits genetic discrimination by life and disability—but not health—insurers. Montana is the most recent entrant in this area, with a new law that bars insurers from refusing to consider applications for life or disability insurance on the basis of a “specific chromosomal or single-gene genetic condition” (Mont. Code Ann. 1991). The statute also classifies as unfair discrimination either the rejection of an application or

the determining of life or disability insurance rates on the basis of a genetic condition, "unless the applicant's medical condition and history and either claims experience or actuarial projections establish that substantial differences in claims are likely to result from the [condition]." The statute is essentially identical to an Arizona law that has been in effect for about 3 years (Ariz. Rev. Stat. 1989).

Some years ago, several states passed statutes that prohibit genetic discrimination in various types of insurance underwriting but that protect carriers of only one or two specific genetic traits. North Carolina bars discrimination by both health and life insurers and by health insurance plans, but the relevant statutes refer only to discrimination against persons with the sickle cell anemia or hemoglobin C traits (N.C. Stat. I 1975). Tennessee likewise bars discrimination based on either of these traits, but only by life insurers (Tenn. Code Ann. 1989). Florida and Louisiana both limit their statutory prohibitions to discrimination, by life and disability insurers, based on the trait for sickle cell anemia (Fla. Rev. Stat. I 1978; La. Rev. Stat. I 1982). In addition, the relevant Louisiana statute expressly permits such insurers to employ waiting periods and preexisting-condition or dread-disease exclusions that do not "unfairly discriminate" against sickle cell trait carriers.

Newly enacted legislation in Wisconsin (Wisc. Act 1991) approaches this problem from a somewhat different perspective, by directly prohibiting insurers from requiring or administering genetic tests, broadly defined, without the prior written and informed consent of the applicant for insurance and by making such conduct criminal. It also prohibits the disclosure, to insurers, of both the fact that a prospective insured has taken a genetic test and the results of any such test, without the person's written, informed consent. In New York, the legislature is considering a bill likewise designed to keep genetic information away from insurance companies from the outset, by prohibiting the disclosure to them of all genetic data (but not, apparently, by preventing them from conducting their own genetic tests) (N.Y. Senate Bill I 1991; N.Y. Assembly Bill I 1991).

In New Jersey, the Department of Health is required by law to consult with the Commissioner of Insurance to identify "arbitrary and unreasonable discrimination against persons with hereditary disorders and their families in insurance coverages" (N.J. Stat. Ann. 1981). The extent to which this requirement has had the effect of curbing potential misuses of genetic information by

insurance companies in that state is, however, unknown. An alternative approach has been suggested in Pennsylvania. There, a resolution currently under consideration would place a 2-year moratorium on insurance companies' practice of using genetic conditions to deny persons insurance coverage; during this moratorium the Pennsylvania Department of Health would carry out a study relating to genetic predisposition and the problem of genetic discrimination in the insurance industry (Penn. Senate Resolut. 1991).

#### *Legislation Relating to Discrimination in Employment*

A growing number of states are enacting, or at least are debating, laws designed to curb the use of genetic testing by employers and related entities and/or to prevent genetic discrimination in the workplace. One of the most ambitious efforts in this area is the legislation recently enacted in Wisconsin (Wisc. Act 1991). The new Wisconsin statute treats genetic testing in employment similar to polygraph testing and prohibits labor organizations, employment agencies, licensing agencies, and employers—including government employers—from soliciting, requiring, or administering a genetic test to any person as a condition of employment, membership, or licensure. Under that law, a person also cannot be terminated from employment, membership, or licensure, or have the terms or conditions of his or her employment, membership, or licensure affected, simply because of a genetic test. The law also bars anyone from "selling" genetic data to employers, labor organizations, and employment or licensing agencies, or from interpreting genetic test results for any such entity. In addition, no one is permitted to offer a person employment, membership, or licensure, or to pay a person any benefit, in return for that person's agreement to submit to a genetic test. The law subjects those who violate its provisions to detailed administrative and judicial enforcement procedures and to the remedies specified under the state's fair-employment law, including reinstatement, back pay, and attorney's fees.

Related provisions of the new Wisconsin law mandate informed consent for all genetic testing in the workplace and prohibit, under pain of criminal penalties, the disclosure of both the fact of genetic testing and any genetic test results without the written, informed consent of the test subject. However, the law does authorize the genetic testing of an employee who requests it and who provides consent, either for purposes of investigating a worker's compensation claim or for determining his or her susceptibility or level of

exposure to potentially toxic chemicals or substances in the workplace.

A bill introduced in the Iowa legislature in early 1992 (Iowa S.B. 2145) sets out employment-related genetic testing prohibitions very similar to those in the Wisconsin statute, while excluding the special criminal provisions on informed consent and disclosure. The Iowa bill also expressly prohibits employers from discharging, disciplining, or discriminating against those who file complaints or testify in proceedings alleging genetic discrimination.

An Oregon law (Or. Rev. Stat. 1988), already in effect, addresses the problem of genetic discrimination in employment by combining within a single prohibition the practice of employer-initiated genetic screening and the workplace administration of breathalyzer, polygraph, brainwave, or psychological stress tests. The Oregon statute, in the part relevant here, makes it an unlawful employment practice for an employer either directly or indirectly to subject any employee or prospective employee to a genetic screening test. Employers who violate this law are subject to the same civil and criminal penalties as are imposed for other unlawful employment practices under Oregon state law.

A Texas bill that was recently proposed but that did not pass (Tex. H.B. 1991) would have made it an unlawful employment practice for an employer to “fail or refuse to hire, discharge, or otherwise discriminate against an individual with respect to compensation or the terms, conditions, or privileges of employment” because of the results of, or a person’s refusal to submit to, genetic screening. The bill defined “genetic screening” to include testing for the sickle cell anemia, hemoglobin C, thalassemia, Tay-Sachs, and cystic fibrosis traits, as well as for “a predisposition for such a disorder or hereditary trait.” The bill also would have prohibited labor organizations from excluding or expelling persons from membership, and employment agencies from refusing to classify or refer persons for employment, in like circumstances. More generally, the Texas bill would have prohibited each of the covered entities from using genetic screening to “limit, segregate, or classify [employees, members, or applicants] for employment or membership in a way that would deprive or tend to deprive [them] of employment opportunities or otherwise adversely affect [their] status.”

New Jersey has taken a similar approach, making it an unlawful employment practice for an employer to discriminate against a person with an “atypical he-

reditary cellular or blood trait” by refusing to hire or employ such a person, barring or discharging such a person, or requiring his or her retirement (N.J. Stat. Ann. 1985). The relevant New Jersey statute defines “atypical hereditary cellular or blood trait” to include the traits for sickle cell anemia, hemoglobin C, thalassemia, Tay-Sachs disease, and cystic fibrosis.

Likewise, New York law forbids denying to an otherwise qualified person equal opportunities to obtain and/or maintain employment and/or advance in position merely because that person has a “unique genetic disorder,” unless it can be “clearly shown” that the disorder would prevent him or her from performing the particular job (N.Y. Civil Rights Law 1990). “Unique genetic disorder” is defined rather narrowly, being limited to persons with sickle cell anemia trait and to carriers of Tay-Sachs disease and Cooley anemia. However, the prohibitions of the New York statute expressly apply to all categories of employers—including state and local governmental employers. A recently introduced New York bill would go further, by prohibiting, in the first instance, the release of all records, findings, and results of genetic testing to employers or potential employers (N.Y. Senate Bill I 1991; N.Y. Assembly Bill I 1991).

As in the insurance context, several states have enacted employment discrimination statutes that reach only one or two specific genetic conditions. North Carolina prohibits genetic discrimination in employment, but only against persons with the sickle cell anemia or hemoglobin C traits (N.C. Stat. II 1975). Florida and Louisiana both prohibit employment discrimination based on the sickle cell anemia trait (Fla. Rev. Stat. II 1978; La. Rev. Stat. II 1982), the Florida law expressly prohibiting screening or testing for that trait as a condition of employment. The Louisiana statute does not expressly disallow testing, but it contains a number of other detailed provisions regulating employer practices (as well as employment agency and union practices) in connection with the treatment of persons with the sickle cell anemia trait.

#### *Legislation Relating to Other Forms of Discrimination*

Although the majority of legislative efforts targeted at the use and misuse of genetic information have focused on the insurance and employment areas, some legislative attention has also been paid to genetic discrimination in other contexts. For example, the same Florida statute that prohibits employers from screening or testing for the sickle cell anemia trait also prohibits the use of sickle cell testing as a condition for

admission to state schools and state-chartered private schools; it further disallows such testing as a condition of eligibility for adopting a child under Florida state law (Fla. Rev. Stat. III 1978; Fla. Rev. Stat. IV 1978; Fla. Rev. Stat. V 1978).

In 1991, the California governor vetoed broad-based legislation designed to prohibit genetic discrimination in a wide variety of contexts (Calif. Assembly Bill 1991). Had it been enacted, this law would have established the right of all persons in California, regardless of their genetic characteristics, to be free from discrimination in “obtaining and enjoying the services, facilities, advantages, housing or other accommodations, or employment opportunities of all business establishments.” The act defined “genetic characteristics” as “any scientifically or medically identifiable gene or chromosome, or alteration thereof, which is known to be a cause of a disease or disorder, or determined to be associated with a statistically increased risk of development of a disease or disorder,” where the person is asymptomatic of any disease or disorder. It would have held persons who violated or aided or incited violations of its terms liable for actual and treble damages and attorney’s fees. Under the act, if there were reasonable cause to believe that a “pattern or practice” of genetic discrimination existed, either the aggrieved person, the California attorney general, or any district or city attorney would have been able to seek an injunction or restraining order to prevent the continuation of the discriminatory practice in question. In vetoing this act, the California governor stated that “[e]mployers fearful of exorbitant health care costs should not be regarded as bigots to be prosecuted, but rather we would seek a solution to this problem which would both encourage testing and not impose an undue cost burden upon employers which more equitably should be spread broadly over all of society” (Governor’s Letter 1991).

## Discussion

### *Critique of the State Legislation*

Genetic information raises issues that go beyond the concerns involved with medical information generally. This is in part because of the immutability of genetic characteristics and because of the fact that genetic information relates not only to the person from whom it is obtained but also to that person’s family members. The examples of legislation summarized above represent a recognition by a growing (albeit still small) number of states that statutory controls are necessary to regulate the conditions under which

genetic information can be acquired, maintained, shared, and used by others.

The laws enacted or considered to date do not, on the whole, follow a particularly coherent pattern. A major deficiency underlying many of the bills and statutes is a failure to define the terms “genetic” or “hereditary” with sufficient breadth. A number of genetic-specific laws—particularly some of the less recently enacted ones—are narrowly drafted to cover only a handful of selected conditions or traits (e.g., sickle cell anemia, hemophilia, and Tay-Sachs disease). A few statutes apply somewhat more broadly to “specific chromosomal or single-gene genetic conditions,” but even these may be too rigid in application and are likely to leave certain data (such as tests that predict enhanced risk for multifactorial disorders) unprotected. The better-drafted laws apply to protect persons with “any hereditary disorder” (Calif. Senate Bill 1991) or any “atypical hereditary cellular or blood trait” (N.J. Stat. Ann. 1985), but even most of these do not define the term “hereditary” with precision, leaving it unclear whether the word applies only to single-gene conditions or also encompasses conditions that are multifactorial in nature. In addition, most genetic-specific laws do not clearly distinguish between carriers of genetic traits and persons who actually experience manifestations of genetic disease.

### *Confidentiality and Informed Consent: Role of the Human Genome Privacy Act (HGPA)*

With the very few exceptions discussed, the state laws dealing with confidentiality and informed consent in the genetic testing context are disease specific or contemplate testing for only a narrow range of genetic conditions. Few of the laws contain enough detail to provide adequate assurances that consent to genetic testing is fully informed. For example, only the proposed California legislation would specially address the issue of testing children, by expressly disallowing such testing to be done over the objection of a parent or guardian. Even this bill, however, does not spell out in detail the requisites for ensuring that consent to a genetic test is actually informed (i.e., what the test subject must be told before the test is given) or provide any guidance on when, if ever, consent to a particular test may be implied. It also (like most other genetic-specific informed-consent laws) is silent on what constitutes informed consent in the research setting.

Most existing statutory provisions addressing the confidentiality of genetic test results are likewise inadequate. These, like the associated pretest informed-consent provisions, tend to be buried within the sec-

tions of state codes that establish screening programs for specific genetic traits (or that set up birth defects registries), and they typically say little more than that the information gathered in such programs shall remain “confidential.” They are almost invariably silent on such issues as to whether there exist conditions under which genetic information may be disclosed to family members who could benefit by receiving it and the procedures for waiving consent to the release of genetic test results. Few laws, with the exception of the recently enacted Wisconsin statute, set out actual penalties for confidentiality violations or establish any detailed enforcement mechanism.

The proposed HGPA pending before the House Committee on Government Operations may, if enacted, cover some areas not addressed by these state genetic-confidentiality laws. The HGPA broadly defines “genetic information” as “any information that describes, analyses, or identifies all or any part of a genome identifiable to a specific individual.” It would (with certain enumerated exceptions) expressly permit individuals access to their *own* genetic information and would give them the opportunity to request correction or supplementation of that information where necessary—allowances conspicuously absent in most of the state laws governing the treatment of genetic data. The bill also would (although, again, with a number of exceptions) prohibit the disclosure of genetic information to third parties without an individual’s signed, written authorization indicating (among other things) the person to whom disclosure may be made, the nature of the information to be disclosed, and the specific purpose of the disclosure. In addition, the HGPA contains special provisions relating to the exercise of genetic-confidentiality rights by incompetent individuals and children of various ages.

Nevertheless, the HGPA provisions are deficient in several respects. The bill is silent on the requirement of what constitutes informed consent to testing, limiting its focus to the regulation of what can be done with genetic test results once they have been obtained. Even more troublesome, the exceptions that riddle the bill’s general prohibition of unauthorized disclosure are so numerous that, collectively, they largely undercut the confidentiality protections the bill is supposed to provide. For example, the HGPA would permit federal agencies to disclose genetic information to “medical professionals” for use “in connection with the care or treatment of a specific individual.” The breadth of this language seems to suggest that genetic data about an individual may be disclosed, without that person’s consent, to health care professionals

treating his or her relatives. While the bill would prohibit the further dissemination of the information (such as to the relatives directly), there is an exception to this in cases where disclosure is required by law or is “necessary to fulfill the purpose for which the information was obtained.” The vagueness of this language suggests that such information could in many instances be further disclosed with impunity—driving a great wedge into the statute’s more general assurances of confidentiality.

Another problem in the HGPA is that it allows disclosure “to alleviate emergency circumstances affecting the health or safety of any individual.” Yet, the bill nowhere defines “emergency,” leaving open the possibility that physicians and courts could give an unduly broad construction to the term. In addition, by referring to the health or safety of “any” individual, the bill potentially opens the door to disclosures to countless recipients. Another exception, permitting disclosure where there are “reasonable grounds” to believe that the information is “needed to assist in the identification of a dead individual, or as an aid to that deceased individual’s relatives,” places no controls on such information once it is in the possession of law enforcement personnel. This opens up the possibility that the data could thereafter be disseminated widely and find their way, over time, into numerous (and presumably all unregulated) data banks. Similarly, the bill’s reference to authorizing disclosure as an “aid to [the] deceased individual’s relatives” is rather vague; under this language, mere curiosity on the part of family members about the genetic makeup of a deceased individual could presumably suffice to justify disclosure.

The HGPA is limited to safeguarding the confidentiality of genetic information maintained by *federal agencies* (or their contractors or grantees). Thus, even if it is enacted, this legislation will not cover genetic data generated in other contexts. The bill also fails to provide any specific remedies or mechanisms for its enforcement. This proposed federal legislation thus does not supplant the need for more comprehensive state genetic-confidentiality and informed-consent legislation than currently exists.

*Genetic Discrimination in Insurance, Employment, and Other Contexts: Role of the Americans with Disabilities Act of 1990 (ADA)*

The few states that have considered or enacted genetic-specific legislation designed to prevent genetic discrimination in insurance have, again, typically limited their prohibitions to a limited number (or cate-

gory) of genetic conditions or traits. They also have typically limited their prohibitions to a limited set of insurance contexts, such as life and disability—but not health—insurance (or vice versa). Currently, only California has broad-based legislation that prohibits genetic discrimination in a wide range of insurance settings. Even the relevant California provisions, however, limit their prohibitions to discrimination against unaffected carriers of genetic traits; they do not extend to limiting an insurer's ability to discriminate against a person who actually manifests a particular genetic condition—even, apparently, in the absence of actuarial justification. The pending New York legislation would disallow the release of genetic information to insurance companies, but it does not prevent insurers from conducting their own genetic tests (or from using genetic data previously obtained) to discriminate against persons with, or perceived to be at risk for developing, genetic disease. The more comprehensive legislation enacted last year in Wisconsin, by contrast, would appear to bar most such activity.

Although most states have general laws that prohibit “unfair discrimination” by both life and health insurers, these laws tend to be phrased too generally to provide adequate protection for asymptomatic individuals whose longevity or future health may be affected by a unique genetic condition. In addition, under the Employment Retirement Income Security Act of 1974 (ERISA), employers who self-insure can effectively avoid these state insurance regulations. People with chronic diseases already often have difficulty obtaining adequate insurance coverage. If advances in genetics reach the point where insurance companies are able, at low cost, to predict who is *likely to become* chronically ill, then increasing numbers of individuals may be caught in the net of those perceived as uninsurable. Insurers may explicitly begin to view certain genetic predispositions as a preexisting condition and may deny coverage.

The recently enacted ADA will probably do little to alleviate the potential for genetic discrimination by insurance companies. Although this federal statute, as discussed below, will probably be invoked successfully against various types of genetic discrimination in employment, it does not speak at all to insurance discrimination. In fact, the ADA expressly disclaims any intent to disrupt insurance arrangements based on risks that may be taken into account under state law or to disrupt any employee benefit plan based on a similar risk assessment. The ADA's lack of inclusion of a

nationwide prohibition on insurance discrimination makes the gaps in the state insurance-discrimination laws discussed above especially troublesome.

The scattered state legislative initiatives designed to regulate the use of genetic data in decisions about employment also leave a number of unfilled gaps. The newly enacted Wisconsin bill provides by far the most comprehensive state prohibition against genetic discrimination in employment. It defines “genetic testing” quite broadly, applies to both public and private employers (and to a variety of other designated entities that routinely make employment-related decisions), prohibits genetic testing as a condition of employment, limits the conditions under which an employer can obtain genetic test results from others, requires informed consent for genetic testing of current employees (and for test result disclosure), and generally prohibits genetically based employment discrimination. It also establishes a detailed enforcement mechanism and lays out specific civil (and, for some types of violations, criminal) remedies for noncompliance.

With the possible exception of the proposed Iowa bill, none of the other laws now in effect or under consideration would go nearly as far as the almost total ban Wisconsin has now imposed. Several of the laws were drafted by legislators who had in mind only discrimination based on the sickle cell trait (or one or two other specific genetic traits), and thus they have no applicability to the vast majority of genetic conditions. Although Oregon law generally prohibits employers from forcing workers or prospective workers to submit to genetic tests, it does not prevent them from obtaining genetic test data from others (e.g., by reviewing an employee's medical records), nor does it appear to prohibit discrimination based on that information. The recently proposed but now defeated Texas bill, while not directly barring genetic testing, would have made it an unfair employment practice for a company (or employment agency or union) to discriminate on the basis of either genetic test results or a refusal to submit to a test and would have offered greater protection in this respect; it, however, would only have applied to testing for a limited number of conditions or traits, and, in that respect, it too was deficient. The New Jersey and New York statutes, which only prohibit genetically based employment discrimination against persons with a finite range of genetic traits or disorders, are similarly deficient. However, other New York legislation still under consideration, which would generally prohibit the release

of genetic data to employers in the first instance, may, if enacted, help to alleviate some of the concerns surrounding the potential for abuse in New York.

The extent to which genetic discrimination in employment is prohibited under the federal ADA remains somewhat unclear. Little attention was paid to genetic discrimination in the legislative hearings on the ADA, and the regulations promulgated under the statute do not explicitly address it. Nonetheless, persons who are *currently disabled* by a genetic disease (i.e., who have a “substantial” limitation on one or more major life activities) are covered by the ADA. It is also likely (although somewhat less certain) that the ADA will limit discrimination against persons who are merely *carriers* of recessive genetic disorders, since the statute’s prohibition of discrimination based on a *perception* of disability would seem to apply to employers who erroneously assume that carriers themselves are (or will become) disabled (Gostin 1991).

Less clear is whether persons who are currently asymptomatic but who are nevertheless *predicted to develop* a genetic disease sometime in the future (e.g., persons with the gene for Huntington disease) are covered by the federal law. Both case law interpreting the Rehabilitation Act of 1973 (Rehabilitation Act) (the counterpart to the ADA, applicable to employers with a nexus to the federal government) and various state disability statutes suggest that it is unlawful to discriminate on the basis of future disability. It would indeed seem anomalous to protect only those who have developed symptoms. Nevertheless, until courts have the opportunity to rule on the applicability of the ADA to currently healthy individuals who are at genetic risk, the extent to which the law can be used to complain of this type of discrimination in the workplace remains uncertain.

The ADA does specifically prohibit employers from conducting pre-job offer medical inquiries, thus limiting their ability to obtain genetic information before a job is offered. While an employer, under the ADA, may make an offer of employment contingent on genetic testing, the testing must be required of all applicants, the results must be kept confidential, and the test cannot be performed until after the job offer has been made. In addition, once an employee is hired, he or she cannot be compelled to submit to a medical examination (including a genetic test) unless it is job related and consistent with business necessity. This aspect of the ADA can be expected to limit significantly many employers’ ability to discriminate against persons who are afflicted with, or at risk of developing,

genetic disease. Still, because the law initially applies only to employers with 25 or more employees (and, after 2 years, will apply only to those with 15 or more employees), many workers will remain unprotected. However, it is precisely the smallest employers who tend to have the greatest concerns about spiraling health care costs and who thus generally may have the most incentive to screen out genetically at-risk workers.

Few states have (or are considering) legislation that would regulate the use or abuse of genetic information in contexts other than insurance and employment. Although Florida has a statute that bars educational discrimination against children with the sickle cell trait, this law does not extend to prevent school systems from discriminating against children with any other genetic conditions, and no other states appear to have enacted any genetic-specific legislation relating to discrimination in educational contexts. Genetic information can also be misused by other institutional entities, such as adoption agencies seeking to prevent adoption by couples or individuals perceived to be at genetic risk or state motor vehicle registration departments seeking to restrict individuals from obtaining driver’s licenses. Although the ADA extends to employment, public services, public accommodations, and telecommunications, no states have yet enacted legislation addressed specifically to these concerns. Thus, few legal impediments exist to prevent genetic discrimination in many of these areas.

#### *Toward Model Legislation*

The articulation of public policy through new legislation is a complex, often slow-moving, and sometimes unpredictable process. Federal laws may be enacted that significantly shape state policy (e.g., through the award of matching funds). But this is as much the exception as the rule. In recent decades, groups such as the National Conference of Commissioners on Uniform State Laws and the National Conference of State Legislatures have worked hard to develop model laws on emerging social issues—an efficient means of achieving relatively uniform laws throughout the 50 states. The increasing number of bills being offered to regulate the flow of genetic data indicate that it would be helpful to identify the key elements of a model law.

As a tentative list, we propose that legislation to safeguard the privacy interests of individuals undergoing genetic testing recognize that unauthorized disclosure of genetic data to third parties may seriously harm

individuals and their families (Billings et al. 1992). The law should define who should be authorized to collect genetic information, and under what circumstances. In addition, it should specify how the information should be stored, and who should control access to it. The law should, however, permit qualified researchers with legitimate protocols to have access to genetic data, so long as the information remains anonymous. Because of the potential harm that may be caused by wrongful disclosure, individuals who, without proper authorization, knowingly or negligently disclose genetic data should be subject to civil liability. In addition, those who, without authorization, knowingly disclose such information should be subject to criminal penalties (Reilly 1992).

### Conclusion

Concurrent with the ever-increasing advances in the ability to conduct diagnostic, presymptomatic, and predispositional tests for a variety of genetic conditions, state-level legislative activity in the areas of genetic confidentiality, informed consent, and discrimination—particularly in the insurance and employment contexts—continues to mount. Although most of these initiatives, like their federal counterparts, represent a step in the right direction, major gaps continue to exist that can only be addressed by comprehensive genetic privacy and discrimination legislation. Policymakers and geneticists should attempt to keep abreast of relevant developments as they occur, as law-making efforts at the state level can strongly influence the development of genetic-related policies nationwide. The proliferation of proposals to regulate genetic data is unlikely to abate soon. The members of The American Society of Human Genetics (ASHG) may serve an important public function by ascertaining relevant legislative activity in their states, by obtaining copies of bills early in the legislative process, and by providing the legislators with a candid analysis of their content.

The board of directors of ASHG should consider asking the Social Issues Committee or an ad hoc committee to study and report on a model approach to regulate the use, by third parties, of genetic information. If such a model were developed, approved by the ASHG, and transmitted to groups such as the National Conference of State Legislators, it could have significant impact.

*Note added in proof.*—Since this article was accepted for publication, Iowa has passed a law that

prohibits genetic discrimination in employment, and similar legislation has been introduced in Ohio, Rhode Island, and New York. The California and Ohio legislatures are also considering new bills relating to genetic discrimination in insurance.

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