An Analysis of the Adequacy of Current Law in Protecting Against Genetic Discrimination in Health Insurance and Employment

A Report Commissioned by the
Secretary's Advisory Committee on Genetics, Health, and Society

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The Secretary's Advisory Committee on Genetics, Health, and Society, http://www4.od.nih.gov/oba/SACGHS.HTM, *wishes to thank the Department of Justice, Department of Labor, Equal Employment Opportunity Commission, and, within the Department of Health and Human Services, the Centers for Medicare & Medicaid Services and the Office for Civil Rights for the technical assistance they provided in the development of this report.*

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EXECUTIVE SUMMARY

INTRODUCTION

One of the findings in the bill entitled, "Genetic Information Nondiscrimination Act of 2005," as introduced in the current sessions of the House and Senate, is that Federal law addressing genetic discrimination in health insurance and employment is incomplete in both the scope and depth of its protections and that State genetic nondiscrimination laws vary widely with respect to their approach, application, and level of protection. This analysis examines pertinent Federal statutes and constitutional protections to determine the extent to which they provide for the confidentiality of genetic information and protect against genetic discrimination and briefly reviews the coverage of State laws.

FEDERAL PROTECTIONS AGAINST GENETIC DISCRIMINATION IN HEALTH COVERAGE

Health Insurance Portability and Accountability Act (HIPAA). This statute, which provides for the portability of employment-related health coverage, prohibits group health plans and group health issuers from: (1) imposing a preexisting condition exclusion on the basis of genetic information unless there is an actual diagnosis of the condition related to the genetic information; or (2) establishing eligibility requirements for any individual based on genetic information or other health-status related factors. In addition, health insurance issuers in the small-group market (employers with 2-50 employees) may not deny issuance of a policy on the basis of the genetic information of any enrollee or potential enrollee and insurers in both the small and large group markets may not refuse to renew a policy based on genetic information about an enrollee or potential enrollee.

However, HIPAA does not restrict a group health plan or issuer from requesting, purchasing, or otherwise obtaining genetic information about an individual or requiring an individual to submit to a genetic test as a condition of coverage and, on the basis of the information obtained, charging all members of the group higher premiums. There are also gaps in the applicability of the preexisting condition exclusion and nondiscrimination provisions, which do not apply to very small plans, retiree-only coverage, and self-insured non-Federal governmental plans that elect to take advantage of a statutory exemption.

The HIPAA nondiscrimination provisions do not apply to individual health insurance policies, even though 10-15 percent of those covered have such policies. HIPAA guarantees certain individuals who lose group health coverage the opportunity to purchase individual coverage without any exclusion based on genetic information, or other preexisting condition, and would prohibit an issuer from refusing to renew an individual policy based on genetic information, but the issuer would not be prohibited from adjusting the premium based on the information.

Social Security Act. In contrast to HIPPA, the statute governing the Medicare supplemental health insurance program (Medigap) does not specifically state that provisions prohibiting discrimination on the basis of health status or medical condition include genetic information.

Title III of the Americans with Disabilities Act. This statute applies to private businesses and provides that no individual shall be discriminated against on the basis of disability in the full enjoyment of the goods, services, facilities, privileges, advantages or accommodations of any place of public accommodation. The prevailing conclusion of decisions in the United States Circuit Courts of Appeal is that this nondiscrimination provision does not apply to insurance policies. In addition, the so-called "safe harbor provision" of the ADA, which provides that the pertinent provisions are not to be interpreted to prohibit or restrict an insurer from underwriting risks, classifying risks, or administering risks that are consistent with State law, has been broadly construed by the courts in favor of the insurers.

FEDERAL PROTECTIONS FOR THE PRIVACY OF GENETIC INFORMATION

The Department of Health and Human Services regulation providing standards for the privacy of individually identifiable health information, including genetic information, does not comprehensively protect the privacy of genetic information. A health care provider is not covered by the regulation if it does not transmit health information in electronic form. Although an authorization from the individual to whom the information pertains is required in order for a covered entity to disclose protected health information to an employer, an employer could contract with a provider not covered by the regulation, obtain genetic test results from the provider, and use and disclose those results without being subject to the regulatory restrictions.

THE EFFECT OF STATE LAW

As of August 2004, forty-seven States and the District of Columbia restricted the use of genetic information to determine health insurance rates or eligibility in group or individual health insurance plans, or both. Widely varying privacy laws that are specific to genetic information have been enacted in twenty-nine States. These statutes are inconsistent in their scope and their definition of genetic information. There is a significant gap in any State's ability to prohibit genetic discrimination by health plans and insurers, because self-insured employee benefit plans are generally exempt from State regulation under the Employee Retirement Income Security Act (ERISA).

PROTECTIONS AGAINST GENETIC DISCRIMINATION IN THE WORKPLACE

State Law

As of August 2004, thirty-two States restricted the use of genetic information in the workplace and nine states were considering legislation addressing that issue. It has been suggested that the inconsistencies in the State laws will impose a substantial burden on companies operating across State lines because of the cost of determining what is permissible in each State.

Federal Law

The Americans with Disabilities Act (ADA). The Equal Employment Opportunity Commission (EEOC) takes the position that the ADA prohibits genetic discrimination and successfully settled its first court action challenging an employer's used of genetic screening of employees.

However, the EEOC has supported legislation prohibiting genetic discrimination, noting that the ADA does not explicitly address genetic discrimination and that it is unclear whether the courts would construe the ADA to protect against such discrimination. No court has yet addressed the applicability of the ADA to genetic discrimination, but recent Supreme Court decisions have interpreted the applicability of the ADA narrowly. Even if a genetic predisposition is determined to be a disability under the ADA, employers may raise several defenses, including that an employee with a genetic predisposition poses a threat to his own health.

Title VII of the Civil Rights Act. Title VII, which prohibits employment discrimination of the basis of race, color, religion, sex and national origin, offers some protection against discrimination on the basis of a person's genetic makeup, when that discrimination disproportionately affects individuals belonging to one of the protected groups. For example, an employer refusing to hire carriers of the genetic mutation for Tay-Sachs disease arguably would be discriminating against persons with an Eastern European Jewish ethnic background—a prohibited disparate impact on the basis of national or ethnic origin.

Right to Privacy and Fourth Amendment Protections. The United States Court of Appeals for the Ninth Circuit has recognized that a person has the highest expectation of privacy in his genetic information and that the Fourth Amendment protection against unreasonable searches and seizures applies both to the taking of a blood sample and to the subsequent analysis of the sample to obtain data. However, these constitutional protections are limited because they apply only to governmental action and the courts will weigh the infringement of individual rights under the Constitution against the public health or other interests of the government in taking the action.

Protections for Federal Employees. Employees of the Federal Government are protected from genetic discrimination by Executive Order 13,145 issued on February 8, 2000. The Executive Order prohibits departments and agencies of the Executive Branch from using protected genetic information to discharge, not hire, or otherwise discriminate against any applicant or employee with respect to compensation or the terms, conditions or privileges of employment. Genetic monitoring of the biological effects of toxic substances in the workplace is permitted if an employee has given knowing and voluntary consent and if the employer learns of the test results only in aggregate terms that do not identify individuals.

CONCLUSION

Currently, there are no Federal laws that directly and comprehensively address the issues raised by the use of genetic information. There are laws and court decisions that address parts of these issues, but they leave substantial gaps in coverage and offer inconsistent safeguards at best. Although individuals who encounter genetic discrimination cannot be said to lack any avenues for relief under current law, many legal commentators agree that those avenues are uncertain and likely to lead to costly litigation, and that current law does not adequately protect against genetic discrimination.

INTRODUCTION

It has been argued that Federal legislation protecting the privacy of genetic information and prohibiting discrimination on the basis of genetic information is not needed because there is insufficient evidence of violations of privacy or genetic discrimination and current law provides sufficient protection. This analysis addresses the latter issue—whether current law provides sufficient protection—by examining pertinent Federal and State laws.

On February 17, 2005, the United States Senate passed the Genetic Information Nondiscrimination Act of 2005, S. 306, by a vote of 98-0 and sent it to the United States House of Representatives. On March 10, 2005, an identical bill was introduced in the House of Representatives as H.R. 1227 and referred to committee. One of the proposed congressional findings in Sec. 2 of the bills states:

> Federal law addressing genetic discrimination in health insurance and employment is incomplete in both the scope and depth of its protections. Moreover, while many States have enacted some type of genetic non-discrimination law, these laws vary widely with respect to their approach, application, and level of protection. Congress has collected substantial evidence that the American public and the medical community find the existing patchwork of State and Federal laws to be confusing and inadequate to protect them from discrimination. Therefore Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies.

This analysis examines pertinent constitutional protections, Federal nondiscrimination statutes, Federal statutes governing health insurance, and Federal statutes governing the privacy of medical records, including regulations and court decisions interpreting those statutes, to determine the extent to which they provide confidentiality and protect against genetic discrimination. State laws that protect the confidentiality of genetic information and restrict its use to determine health insurance eligibility or rates are examined briefly to determine the extent to which those laws provide uniform, comprehensive protections.

FEDERAL PROTECTIONS AGAINST GENETIC DISCRIMINATION IN HEALTH COVERAGE

In 2003, approximately 84 percent of the population had health coverage, and approximately 60 percent of the population had employment-based health coverage,[1] mostly group plans.[2] Roughly 10-15 percent of those who are covered purchase individual policies.[3] About 50-60

[1] United States Census Bureau, Health Insurance Coverage: 2003. http://www.census.gov/hhes/www/hlthins/hlthin03/hlth03asc.html

[2] Jennifer S. Geetter, Coding for Change: The Power of the Human Genome to Transform the American Health Insurance System, *28 Am. J. L. and Med. 1, 44 (2002).*

[3] *Id.*

percent of employer group plans are self-insured plans under which the employer assumes the risk and becomes the insurer.[4] Under insured employment-based health plans, the employer contracts with a commercial insurance carrier to provide insurance. Generally, employee benefits provided through an employer are governed by the Employee Retirement Income Security Act (ERISA) of 1974, whether insured or self-insured.[5] Insured coverage is also subject to State insurance law, in addition to ERISA. However, employee benefits provided by a State or local governmental employer are not subject to ERISA.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, provides for the portability of health insurance by ensuring in some circumstances that individuals who change health coverage do not have new employment-related coverage denied or unduly restricted on the basis of preexisting conditions. HIPAA added section 701 of ERISA, section 2701 of the Public Health Service Act (PHS Act), and section 9801 of the Internal Revenue Code (the Code) to prohibit group health plans and group health insurance issuers from imposing a preexisting condition exclusion on the basis of genetic information, unless there is an actual diagnosis of the condition related to the genetic information.[6] Thus, if an individual tests positive for a mutation in the gene linked to breast cancer, that information cannot be treated as a preexisting condition in the absence of a diagnosis of breast cancer.[7]

In addition, HIPAA added section 702 of ERISA, section 2702 of the PHS Act, and section 9802 of the Code to prohibit group health plans and group health insurance issuers from establishing eligibility requirements for any individual based on genetic information, medical history, receipt of health care, and other health status-related factors relating to the individual or a dependent of the individual.[8] Under regulations that became effective on May 8, 2001, eligibility

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[4] *Id.* at 46.

[5] *Id.*

[6] 29 U.S.C. 1181(a), 42 U.S.C. 300gg(a), and 26 U.S.C. 9801(a) permit a preexisting condition exclusion to be imposed only if medical advice, diagnosis, care, or treatment for the condition was recommended or received within the 6-month period ending on the enrollment date, the exclusion extends for a period of not more than 12 months (or 18 months for a late enrollee) after the enrollment date, and the period of the exclusion is reduced by the aggregate of the periods of creditable coverage. 29 U.S.C. 1181(b)(1)(A), 42 U.S.C. 300gg(b)(1)(A), and 26 U.S.C. 9801(a) define "preexisting condition exclusion" to mean a limitation or exclusion of benefits relating to a condition that was present before the date of enrollment, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date.
29 U.S.C. 1181(b)(1)(B), 42 U.S.C. 300gg(b)(1)(B), and 26 U.S.C. 9801(b)(1)(b) provide that genetic information shall not be treated as such a condition in the absence of a diagnosis of the condition related to the genetic information.

[7] Marisa Anne Pagnattaro, Genetic Discrimination and the Workplace: Employee's Right to Privacy v. Employer's Need to Know, *39 Am. Bus. L. J. 139, 166 (2001).*

[8] In addition to the HIPAA nondiscrimination provisions, ERISA section 510 may provide some additional protections against discrimination based on genetic information. ERISA section 510 provides, in pertinent part, that "it shall be unlawful for any person to discharge, fine, suspend, expel, discipline, or discriminate against a participant or beneficiary for exercising a right to which he is entitled under the provisions of an employee benefit

requirements include, but are not limited to, rules relating to enrollment, the effective date of coverage, waiting (or affiliation) periods, late and special enrollment, eligibility for benefit packages, benefits, continued eligibility, and terminating coverage of any individual under the plan.[9] HIPAA and the implementing regulations prevent group health plans and issuers from using health status-related factors to charge an individual a premium or contribution greater than that charged a similarly situated individual; they do not prevent an entire group from being charged more.[10]

HIPAA also generally requires all health insurance issuers to offer every small-group policy they actively market in the small-group market to every small employer (i.e., employers with 2-50 employees).[11] Under this provision, an issuer could not deny a policy to a small employer based on any genetic information of any enrollee or potential enrollee. However, this prohibition does not apply to policies sold to large employers (those with more than 50 employees). In addition, HIPAA generally requires health insurance issuers in the small-group market and the large-group market to renew each employer's group health insurance policy, at the option of the employer.[12] This provision would prohibit an issuer from refusing to renew a policy based on genetic information about an enrollee or potential enrollee. However, HIPAA does not restrict an issuer from taking genetic information into account when determining the employer's overall premium.

As stated in the preamble of the *Federal Register* notice promulgating the interim regulations, plans and benefits that are not subject to the HIPAA portability provisions are not subject to the HIPAA nondiscrimination requirements.[13] Thus, the genetic nondiscrimination requirements do not apply to benefits that are excepted under the HIPAA portability provisions, including group health plans with fewer than two participants who are current employees on the first day of the plan year (including retiree-only plans); self-insured non-Federal governmental plans that elect, under 45 CFR 146.180, to be exempt from the nondiscrimination requirements; and certain church plans that are treated as not violating the HIPAA nondiscrimination provisions if the plan requires evidence of good health for the coverage of certain individuals.[14]

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plan...[or ERISA]...for the purpose of interfering with the attainment of any right to which such participant may become entitled under the plan...[or ERISA]."

[9] 66 Fed. Reg. 1378, 1380 (January 8, 2001) amending 26 CFR Part 54, 29 CFR Part 2590 and 45 CFR Part 146.

[10] 29 U.S.C. 1182(b), 42 U.S.C. 300gg-1(b), and 26 U.S.C. 9802(b); Conference Report on Pub. L. 104-191 (HIPAA) H.R. Rep. 104-736 at 179-180 (104th Cong. 2d Sess. 1996).

[11] 45 CFR 146.150.

[12] 45 CFR 146.152.

[13] 66 Fed. Reg. 1378, 1379 (January 8, 2001).

[14] *Id.*

It has been suggested that the HIPAA protections against genetic discrimination are a piecemeal solution to concerns about the misuse of genetic information.[15] The nondiscrimination provisions do not prohibit a group health plan or issuer from requesting, purchasing, or otherwise obtaining genetic information about an individual or requiring that individual to submit to a genetic test as a condition of coverage and, on the basis of the genetic information obtained, charging all members of the group higher premiums.[16] Charging higher premiums could make health insurance too costly for small employers[17] and thus have the same effect as denying coverage.[18] There are also notable gaps in the applicability of the preexisting condition exclusion and nondiscrimination provisions, which do not apply to very small plans, retiree-only coverage, and self-insured non-Federal governmental plans that elect to take advantage of an exemption provided by the statute. Nor does HIPAA address the larger issues raised by gathering and using genetic information in the workplace outside the health insurance context.[19]

More significantly, the HIPAA nondiscrimination provisions do not apply to individual health insurance policies, even though 10-15 percent of those covered have such policies[20] and the number of Americans seeking insurance outside of employment is likely to increase.[21] HIPAA, however, does guarantee certain individuals who lose group health plan coverage the opportunity to purchase a choice of individual coverage, without any preexisting condition exclusion. Under these provisions, a qualifying individual could not be denied coverage based on genetic information. However, HIPAA does not prohibit issuers from taking health factors, including genetic information, into account when determining the individual's premium. HIPAA also generally requires health insurance issuers in the individual market to renew each individual policy, at the option of the policyholder.[22] This provision would prohibit an issuer from refusing to renew a policy based on genetic information about a policyholder, but would not prohibit the issuer from adjusting the premium based on such information.

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[15] Pagnattaro, *supra,* note 7, at 167.

[16] *Id.,* citing U.S. Senate, Opening Statement of Chairman James M. Jeffords, Hearing on Genetic Information and Health, at http://www.senate.gov/labor/hear/05218hrg/jeffords.htm (May 21, 1998); Joanne L. Hustead & Janlori Goldman, The Genetics Revolution: Conflict, Challenges and Conundra, *28 Am. J. L. and Med. 285, 292 (2002).*

[17] *Id.*

[18] Bryce A. Lenox, Comment, Genetic Discrimination in Insurance and Employment: Spoiled Fruits of the Human Genome Project, *23 U. Dayton L. Rev. 189, 208 (1997).*

[19] Pagnattaro, *supra*, note 7 at 167.

[20] Geetter, *supra*, note 2 at 44; Lenox, *supra*, note 18 at 208.

[21] Jeffords statement, *supra*, note 16. H.R. 37, introduced in the House of Representatives on January 4, 2005, encourages the purchase of individual health insurance. It allows a federal income tax deduction for premiums paid under a high deductible health plan by an individual eligible for the deduction of amounts paid into a health savings account.

[22] 45 CFR 148.122.

Social Security Act

Federal law sets national standards for Medicare supplemental (Medigap) policies, which are health insurance policies that cover out-of-pocket costs under Medicare, such as coinsurance and deductibles, as well as specified costs not covered by Medicare. Under certain circumstances, Medicare beneficiaries are given a "guaranteed issue" right. Specifically, Medigap issuers are prohibited from conditioning the issuance or effectiveness of a Medicare supplemental policy, or discriminating in the pricing of the policy, because of "health status, claims experience, receipt of health care, or medical condition" of the applicant.[23] The terms "health status" or "medical condition" might be interpreted to include genetic information. However, in contrast to the HIPAA statute, which, as noted previously, specifically states that "health status-related factor" includes genetic information, the Medigap statute does not specifically state that "health status" or "medical condition" includes genetic information. Also, if an individual wishes to purchase a Medigap policy other than when a guaranteed issue right applies under the statute, the issuer is not precluded from "underwriting," which could include denying a person a policy, or basing the premium on health status, claims experience, receipt of health care, or medical condition.

In instances described above where a Medigap issuer is required to sell a policy, the issuer "may not impose an exclusion of benefits based on a preexisting condition..."[24] The Medigap statute does not define the term "preexisting condition" as it applies to genetic information. In sum, there is significant ambiguity about how the statutory provisions governing Medigap policies apply to genetic information.

Title III of the Americans with Disabilities Act (ADA)

Title III of the ADA, which applies to private businesses, provides that no individual shall be discriminated against on the basis of disability in the full enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation.[25] Places of public accommodation include insurance offices,[26] and numerous Federal district court decisions and legal commentators have concluded that Title III requires equal access not only to physical facilities but also to goods and services, including insurance policies.[27] However, the United States Courts of Appeal in

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[23] 42 USC 1395ss(s)(2)(A), (s)(3)(A).

[24] 42 USC 1395(s)(3)(A)(iii).

[25] 42 U.S.C. 12182(a).

[26] 42 U.S.C. 12181(7)(F).

[27] Catherine Olender, Capping AIDS Benefits: Does Title III of the ADA Regulate the Content of Insurance Policies?, *28 Am. J. L. and Med. 107, 110-11 (2002)*. The Department of Justice (DOJ) regulation at 28 CFR Part 36 is somewhat ambiguous on the issue of coverage of insurance policies and insurance underwriting, but the

the Third, Fifth, Sixth, Seventh, and Ninth Circuits have held that Title III of the ADA does not regulate the content of insurance policies.[28] Only the United States Courts of Appeal for the First and Second Circuits have concluded that the ADA regulates the content of insurance policies.[29]

Even if the prevailing view that Title III does not apply to the content of insurance policies were reversed through a decision of the United States Supreme Court (the Court),[30] the potential effect of Title III on any genetic discrimination in insurance policies would be uncertain. First, as discussed in detail below under the discussion of the applicability of Title I of the ADA to genetic discrimination in the workplace, it is questionable whether a genetic predisposition qualifies as a disability under the ADA. In addition, the so-called "safe harbor provision" of the ADA provides that Titles I-IV of the ADA are not to be construed to prohibit or restrict an insurer from underwriting risks, classifying risks, or administering risks that are based on or are consistent with State law.[31] However, these actions may not be used as a subterfuge to evade the purposes of Titles I and III of the ADA.[32] The Senate and House Committee reports further explain these provisions as follows:

> [A] plan may not refuse to insure, or refuse to continue to insure, or limit the amount, extent, or kind of coverage available to an individual, or charge 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.[33]

Thus, under the interpretation set forth in the Committee reports, a health insurer could deny coverage or charge higher premiums on the basis of the results of genetic testing if that action had a sound actuarial or experiential (actual or reasonably anticipated) basis and was consistent with State law. Most courts that have addressed the issue have adopted an interpretation of the

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preamble to the Federal Register publication of the final rule (published at 56 FR 35546 on July 26, 1991 and republished as Appendix B, 45 CFR Part 36) clearly states that the prohibition on discrimination applies to insurance underwriting practices and the terms of insurance contracts.

[28] Jill Alesch, Note: The Americans with Disabilities Act: An End to Discrimination Against HIV/AIDS Patients or Simply Another Loophole to Bypass? *53 Drake L. Rev. 523, 532 (2004).*

[29] *Carparts Distribution Ctr., Inc. v. Auto. Wholesaler's Ass'n,* 37 F.3d 12, 20 (1st Cir. 1994); *Pallozzi v. Allstate Life Ins. Co.,* 198 F.3d 28, 31-35 (2d Cir. 1999).

[30] In 2000 the Supreme Court declined review of *Doe v. Mut.* of *Omaha Ins. Co.,* 179 F.3d 557 (7th Cir. 1999) which held that Title III does not apply to the content of the goods or services, specifically an insurance policy, offered by a place of public accommodation.

[31] Section 501(c) of the Americans with Disabilities Act, 42 U.S.C. 12201(c).

[32] *Id.*

[33] H.R. Rep. No. 101-485, pt. 2, at 136-37, reprinted in 1990 U.S.C.C.A.N. 303, 420; S. Rep. No. 101-116 at 85. This interpretation is adopted in section 111-3.11000 of the Department of Justice ADA Title III Technical Assistance Manual. www.usdoj.gov/crt/ada/taman3.html

safe-harbor provision that is even more difficult for plaintiffs to overcome than that set forth in the Committee reports. The Second Circuit, for example, has held that if an insurance provision "is consistent with state law and was adopted prior to the passage of the ADA, it is exempt from regulation under the Act pursuant to the safe harbor provision of Section 501(c), regardless of whether it was based on actuarial experience."[34] Other circuits are in agreement that the safe-harbor provision does not require that an insurance provision have an actuarial justification.[35] When the obstacle presented by the safe-harbor provision follows the first obstacle of the prevailing legal authority against applying Title III to the content of insurance policies, it is apparent that Title III is not a viable vehicle for preventing genetic discrimination in health insurance.

FEDERAL PROTECTIONS FOR THE PRIVACY OF GENETIC INFORMATION

There are Federal statutes that protect certain kinds of health or other personal information,[36] but there is no Federal genetic privacy statute. We focus on the U.S. Department of Health and Human Services (HHS) regulation providing standards for the privacy of individually identifiable health information (authorized by HIPAA) because it establishes for the first time a floor of national protections for the privacy of health information, including genetic information.[37] The regulation, which protects the confidentiality of "protected health information," was issued as a final rule on December 28, 2000 (65 Fed. Reg. 82462) and amended on August 14, 2002 (67 Fed. Reg. 53182). The regulation applies to "covered entities," defined as a health plan, a health care clearinghouse, and a health care provider that transmits any health information in electronic form in connection with a transaction covered by HIPAA regulations.[38] The term "health plan" is defined broadly to include group and individual insurers, health maintenance organizations (HMOs), and specified government-funded programs.[39] Most covered entities had to comply with the amended regulation by April 14, 2003, and small health plans had to comply by April 14, 2004.[40]

The regulation restricts health plans and other covered entities in their use and disclosure of "protected health information," defined as individually identifiable health information transmitted or maintained in any form or medium.[41] The term "health information" is defined at

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[34] *Leonard F. v. Israel Discount Bank of New York*, 199 F.3d 99, 106 (2d Cir. 1999).

[35] See *e.g., EEOC v. Aramark Corp., Inc.*, 208 F.3d 266, 271 (D.C. Cir. 2000); *Rogers v. Department of Health and Envtl. Control*, 174 F.3d 431, 437 (4th Cir. 1999).

[36] For example, the Privacy Act, 5 U.S.C. 552a, protects health and other personal information that is maintained in Federal systems of records.

[37] See 67 Fed. Reg. 53182 (August 14, 2002).

[38] 45 CFR § 160.103.

[39] 45 CFR § 160.102.

[40] 45 CFR § 164.534.

[41] 45 CFR § 164.501.

45 CFR § 160.103 to mean any information, whether oral or recorded, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and that "relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual." This definition encompasses genetic information, including family history.[42] Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not covered by the regulation because it is not within the definition of protected health information.[43]

A covered entity may not use or disclose protected health information except as the regulation permits or requires or as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing.[44] A covered entity must disclose protected health information to individuals or their personal representatives when they request access to, or an accounting of disclosures of, their information or to HHS when it is conducting a compliance investigation or review or enforcement action.[45] Among the permitted uses and disclosures without a written authorization are (1) for treatment, payment, or health care operations, except that "authorization" (written consent that meets the requirements of the regulation) is required for most uses or disclosures of psychotherapy notes and most disclosures of protected health information for marketing purposes;[46] (2) where required by law;[47] (3) for specified public health activities;[48] (4) for law enforcement purposes;[49] and (5) for research, if the covered entity obtains documentation that an institutional review board or privacy board has waived authorization, the information will be used only for reviews preparatory to research, or the information relates only to deceased individuals.[50] The regulation imposes various limitations on the uses and disclosures

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[42] Standards For Privacy Of Individually Identifiable Health Information, Miscellaneous Frequently Asked Questions About The HIPAA Privacy Rule, 65 Fed. Reg. 82462, 82621 (December 28, 2000).

[43] 45 CFR § 164.514(a).

[44] 45 CFR § 164.502(a). In order to be valid, a written consent or "authorization" must describe the information to be disclosed or used; identify the person(s) or class of persons authorized to make the disclosure or use, as well as those who will receive the disclosure; describe the purpose of the disclosure or use; set forth an expiration date or event; inform the individual of his/her right of revocation, the extent to which treatment or other benefits can be conditioned on the authorization, and the extent to which the disclosed information may be redisclosed by the recipient; be signed and dated by the individual or his/her personal representative; and otherwise meet the requirements of 45 CFR § 164.508(a)(3)(ii), (c)(1) and (c)(2), as applicable.

[45] 45 CFR § 164.502(a)(2).

[46] 45 CFR § 164.506 and 164.508.

[47] 45 CFR § 164.512(a).

[48] 45 CFR § 164.512(b).

[49] 45 CFR § 164.512(f).

[50] 45 CFR §164.512(i). Other permissible uses and disclosures without authorization are prescribed in 45 CFR § 164.512, including reporting of abuse, neglect, or domestic violence; health oversight activities; to avert a

that are permitted without authorization. These limitations are designed to restrict the scope of the disclosure, limit the potential for further disclosures, and otherwise ensure that the use and disclosure are the minimum necessary to accomplish the intended purpose.[51]

Although the regulation has been characterized as an "extremely important first step" to ensure that those performing core health functions meet basic requirements for the protection of privacy,[52] it does not comprehensively protect the privacy of genetic information. Significantly, with respect to the use of genetic information in decisions about health coverage, the regulation allows a covered entity to use protected health information without consent for its own "health care operations,"[53] including underwriting.[54] Also, a health care provider that is not a covered entity because it does not transmit health information in electronic form may use and disclose genetic information and other health information without regard to the regulation, although there may be other State or Federal laws that restrict such activity. Health care providers that fall into this category might include employers who provide on-site health care to their employees.[55] Although an authorization from the individual to whom the information pertains would be required in order for a covered entity to disclose protected health information to an employer,[56]

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serious threat to health or safety; in response to an order or lawful process in a judicial or administrative proceeding; certain disclosures about decedents; and disclosures for specialized government functions such as military and veterans activities, national security and intelligence activities, protective services for the President and others, and disclosures in connection with law enforcement custodial situations.

[51] In addition to these specific limitations, the regulation imposes a general "minimum necessary" limitation on all disclosures and uses, except for those to a health care provider for treatment; to the individual to whom the information pertains; made pursuant to an authorization; to HHS; and those required for compliance with the regulation or otherwise required by law.
45 CFR § 164.502(b).

[52] Hustead & Goldman, *supra,* note 16 at 292.

[53] 45 CFR § 160.501 defines the term "health care operations" to include underwriting, premium rating, and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits and ceding, securing, or placing a contract of reinsurance of risk relating to claims for health care; provided that, if a health plan receives protected health information for any of these purposes and the insurance or benefits are not placed with that plan, the plan may not use or disclose the information for any other purpose, except as may be required by law.

[54] 45 CFR § 164.506 (c)(1) permits a covered entity to use or disclose, without authorization or consent, protected health information for its own health care operations. Under paragraph (c) (4) a covered entity may disclose protected health information to another covered entity for certain health care operations activities if each entity either has or had a relationship with the individual who is the subject of the record, but those health care operations activities may not include underwriting.

[55] Hustead & Goldman, *supra,* note 16 at 291.

[56] 67 Fed. Reg. 53192 (August 14, 2002). Under 45 CFR § 164.504(f)(1)(ii) an employer that is the sponsor of a group health plan may obtain summary health information from the plan without authorization or consent if it is requested for the purpose of obtaining premium bids from health plans for providing coverage under the group health plan or modifying, amending, or terminating the plan. Although summary health information might include genetic information, that information could not include any identifiers. Under paragraph (f)(1)(iii) an employer-sponsor may also obtain without authorization or consent information about whether an individual is participating in the plan or is enrolled or disenrolled. In order for an employer-sponsor to obtain any other protected health information from a group health plan, the plan documents would have to be amended to ensure that use of the

an employer could contract with a provider not covered by the regulation, obtain the test results from the provider, and use and disclose those results free of any of the restraints imposed by the regulation.[57]

These limitations on the applicability of the HIPAA regulation to those who have genetic information have led to the conclusion that a statutory framework to protect genetic information directly, regardless of who is holding the information, would be more effective in ensuring the protection of that information.[58]

THE EFFECT OF STATE LAW

As of August 2004, 47 states and the District of Columbia restricted the use of genetic information to determine health insurance rates or eligibility in group or individual health insurance plans or both.[59] However, these statutes are inconsistent in their scope and their definition of genetic information (some exclude family history from the definition), and a few apply only to group health insurance.[60] Furthermore, there is a significant gap in any State's ability to prohibit genetic discrimination by health plans and issuers, because self-insured employee benefit plans typically provided to employees as part of their employment benefits are generally exempt from State regulation under ERISA.[61] Thus, only a law at the Federal level

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information by the plan sponsor is consistent with the regulation. 45 CFR § 164.504(f)(1)(i). The employer could not use the information to make employment decisions and would be otherwise restricted in the disclosure and use of the information.

[57] Under the ADA covered employers are restricted in the use of medical examinations or inquiries to discriminate against a qualified individual with a disability (because of the disability) in regard to job application procedures; the hiring, advancement, or discharge of employees; employee compensation; job training; and other terms, conditions, and privileges of employment. 42 U.S.C. 12112(a) and (d). A covered employer may (1) make preemployment inquiries into the ability of an applicant to perform job-related functions; (2) require a medical examination or inquiry after an offer of employment, but before the applicant starts work, and condition employment on the results, if all entering employees in the same job category are subject to the same examination regardless of disability and the information obtained is maintained in separate medical files and treated as a confidential medical record; and (3) require a medical examination or inquiry of an employee that is job-related and consistent with business necessity, if the information obtained is maintained in separate medical files and treated as a confidential medical record. 42 U.S.C. 12112(d); 29 CFR § 1630.14. Confidential medical information may be disclosed to supervisors and managers for the purpose of determining needed accommodations or restrictions on the duties of the employee, to first aid and safety personnel if the disability might require emergency treatment, and government officials investigating compliance with the regulation.

[58] Hustead & Goldman, *supra,* note 16, at 291; S. Rep. 108-122 on S. 1053 at 10-11, 108th Cong., 1st Sess. (2003).

[59] Alissa Johnson, Genetics and Health Insurance (August 2004), National Conference of State Legislatures, http://www.ncsl.org/programs/health/genetics/genbriefs.htm. Mississippi, Washington, and Pennsylvania do not have such laws.

[60] Ashley M. Ellis, Comment: Genetic Justice: Discrimination by Employers and Insurance Companies Based on Predictive Genetic Information, *34 Tex. Tech L Rev. 1071, 1079-80 (2003).*

[61] S. Rep. 108-122, *supra*, note 58 at 12; Ellis, *supra*, note 60 at 1073.

could provide comprehensive prohibitions against genetic discrimination in all areas of health insurance.[62]

Widely varying privacy laws that are specific to genetic information have been enacted in 29 States.[63] These laws, with the exception of the State of Washington, share the characteristics of (1) treating genetic information differently from other medical records; (2) focusing on the information rather than on the user or use; (3) relying on various measures to safeguard genetic information at different stages of its acquisition and retention; and (4) providing for greater individual control over personal genetic information through varying means, such as consent requirements, rights of access, civil remedies, and property rights.[64] Washington became the first State to treat genetic information the same as other health data under privacy laws, by adding genetic information to the definition of protected health information.[65] To the extent that these State laws that apply specifically to genetic information and other State laws that protect the privacy of medical records provide privacy protections that are in addition to, and not contrary to, those in the HIPAA privacy regulation, or regulate people or entities that are not covered by that regulation, people in those States will be afforded additional protections.[66]

The gaps in the protection of the confidentiality of genetic information under HIPAA, the HIPAA privacy regulation, State laws, and the often complex interaction of Federal and State laws create a patchwork of protection for genetic information that may leave patients, health care providers, and health insurers in doubt about the viability and extent of that protection.

PROTECTIONS AGAINST GENETIC DISCRIMINATION IN THE WORKPLACE

State Law

As of August 2004, thirty-two states restricted the use of genetic information in the workplace and nine states were considering legislation addressing that issue.[67] Most of these state laws establish greater protection for genetic information than other health data.[68] In general, the laws permit employer access, acquisition, or use of genetic information in narrowly defined "job-

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[62] S. Rep. 108-122, *supra*, note 58 at 12.

[63] Alissa Johnson, Genetic Privacy (August 2004), National Conference of State Legislatures. http://www.ncsl.org/programs/health/genetics/genbriefs.htm

[64] *Id.*

[65] *Id.*

[66] Hustead & Goldman, *supra*, note 16 at 292-93.

[67] Alissa Johnson, Genetics and Employment (August 2004) National Conference of State Legislatures, http://www/ncsl.org/print/health/genetics/geneticsemploy2004.pdf

[68] *Id.* This special treatment for genetic information is referred to as "exceptionalism."

related" situations, such as job function tests, safety tests, or to investigate a worker's compensation claim.[69]

As noted above in the discussion of state laws limiting genetic discrimination in health insurance, the definitions of genetic information vary significantly from state to state. It has been suggested that this and other inconsistencies in the state laws will impose a substantial burden on companies operating across state lines because of the cost of determining what is permissible in each State.[70]

Federal Law

I. The Americans with Disabilities Act (ADA)

There is no Federal law that directly protects against genetic discrimination in employment, but some protection is provided through laws that prohibit discrimination in employment on the basis of a disability. The ADA protects individuals who have a physical or mental impairment that substantially limits them in a major life activity, who have a record of such an impairment, or who are regarded as having such an impairment.[71] The Act covers all private employers having 15 or more workers, labor organizations, employment agencies, and State and municipal government employers.[72] Section 501 of the Rehabilitation Act, 29 U.S.C. 791, which prohibits disability discrimination against Federal employees, has the same definition of disability as the ADA; thus, this analysis of whether the ADA applies to genetic discrimination also applies to the Rehabilitation Act.[73]

A. Limitations on the ADA's Coverage of Disability Discrimination

The ADA covers present and past impairments, but not future ones. Accordingly, coverage of a genetic predisposition to a disease or disorder would have to be based either on the conclusion that the predisposition itself is a current impairment, even though no impairment exists until the disease or disorder develops,[74] or on the argument that the employer is regarding the individual

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[69] *Id.* Six states, however, require any part, including employers to obtain consent before access or acquiring an individual's genetic information.

[70] Nicole Silvestri, Comment: Echazabal and the Threat to Self-Defense: The Most Recent Call for a Consistent, Interstate Genetic Nondiscrimination Policy, *7 U.Pa. J. Lab & Emp. L. 409, 421 (2005).*

[71] 42 U.S.C. § 12102(2)(A)-(C).

[72] *Id.* §12111(5)(A).

[73] Although Executive Order 13,145 prohibits genetic discrimination in Federal employment, the Order includes no enforcement mechanism. Each agency is responsible for addressing complaints of genetic discrimination and decisions filed by its own employees. Any effort to raise a genetic discrimination claim in court would require reference to the Rehabilitation Act, which, as the following discussion indicates, would be of limited utility.

[74] Roger Clegg, Bragdon v. Abbott, Asymptomatic Genetic Conditions, and Antidiscrimination Law: A Conservative Perspective, *3 J. Health Care L. & Pol'y 409, 410 (2000).*

as having a current disability. If a genetic predisposition were deemed a current physical impairment, the ADA would cover it only if it substantially limits some major life activity.[75]

ADA legislative history and the Equal Employment Opportunity Commission (EEOC), which enforces and interprets the ADA, suggest that the Act was intended to protect against genetic discrimination.[76] In 1995, the EEOC issued a Compliance Manual chapter addressing the definition of "disability." One section of that chapter examined the third component, or prong, of the definition, "regarded as having a substantially limiting impairment." According to the EEOC, this prong would protect individuals who are subject to discrimination on the basis of genetic information relating to illness, disease, or other disorders.[77] The Compliance Manual provides the following example:

> CP's genetic profile reveals an increased susceptibility to colon cancer. CP is currently asymptomatic and may never in fact develop colon cancer. After making CP a conditional offer of employment, R learns about CP's increased susceptibility to colon cancer. R then withdraws the job offer because of concerns about matters such as CP's productivity, insurance costs, and attendance. R is treating CP as having an impairment that substantially limits a major life activity. Accordingly, CP is covered by the third part of the definition of "disability."[78]

Some legal scholars believe that this interpretation finds support in the decision of the United States Supreme Court in *Bragdon v. Abbott*,[79] although that case concerned a "prong one" allegation of discrimination based on an actual disability. In that case, the Court held that asymptomatic human immunodeficiency virus (HIV) infection constituted a disability under the ADA because it is a physical impairment that limits the major life activity of reproduction.[80] The Court determined that Ms. Abbott had demonstrated that HIV status was a substantial limitation in her decision not to procreate, because of concerns about risk to her partner and risk to the child in childbirth. The Court did not address whether other HIV-positive individuals would be covered;[81] nor did the Court examine whether Ms. Abbott also could have pressed her discrimination claim under the "regarded as" prong of the definition of "disability."

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[75] *Id.* Clegg argues that if the possibility of future impairments were deemed a substantial limitation on major life activities, the statute would be stretched to the breaking point and that everyone would be considered disabled.

[76] See statements of Representatives Owens, Edwards and Waxman, 136 Cong. Rec. H4623, H4624-25, H4627 (daily ed. July 12, 1990); EEOC Compliance Manual § 902.8, Order 915.002, 902-45 (1995).

[77] EEOC Compliance Manual § 902.8, Order 915.002, 902-45 (1995).

[78] *Id.*

[79] 524 U.S. 624 (1998). See Paul S. Miller, Is There a Pink Slip in My Genes? Genetic Discrimination in the Workplace, *3 J. Health Care L. & Pol'y 225, 243-44 (2000)*; *but* see Laura F. Rothstein, Genetic Discrimination: Why Bragdon does not Ensure Protection, *3 J. Health Care L. & Pol'y 330, 331 (2000).*

[80] *Bragdon v. Abbott*, 524 U.S. 624, 637-41 (1998).

[81] *Id.* at 639-42.

Arguably, a genetic predisposition to certain diseases or disorders may affect an individual's decision whether to engage in reproduction, a major life activity.[82] A genetic predisposition to disease or disorder has been distinguished from asymptomatic HIV infection, however, on the basis that the latter causes immediate damage to the body, while the former does not. The Supreme Court appeared to recognize this distinction, stating that "In light of the immediacy with which the virus begins to damage the infected person's white blood cells and the severity of the disease, we hold it is an impairment from the moment of infection."[83] Whether this also is true for asymptomatic genetic conditions is uncertain; one legal scholar has argued that the Court's reasoning could be applied to such conditions because science may be able to demonstrate that those conditions create abnormalities in the person's bodily systems or changes on a cellular level.[84] The EEOC also has argued, in policy guidance on genetic discrimination, that a gene alteration associated with a severe disease or disorder is covered under the actual impairment prong of the definition of disability, based on the interpretation that impairment means any physiological disorder and that an alteration in a gene causes cellular and molecular changes leading to disturbances in cell function.[85]

Clearly, defining impairment to cover a purely genetic anomaly would constitute a significant stretching of the term, and no court has reached this conclusion. Moreover, Supreme Court cases decided since *Bragdon* cast serious doubt on the likelihood that the ADA covers an individual with a genetic predisposition to disease or disorder.[86]

In the cases of *Sutton v. United Air Lines, Inc.*,[87] *Murphy v. United Parcel Service, Inc.*,[88] and *Albertsons, Inc. v. Kirkingburg*,[89] the Supreme Court significantly narrowed the scope of the ADA. Specifically, the Court closely examined the text of the ADA and determined that its coverage was limited. Because the phrase "substantially limits" appears in the first prong of the definition in the present indicative verb form, the Court ruled that the language properly should be read as requiring that a person presently, not potentially or hypothetically, be substantially limited in order to demonstrate a disability. A disability exists only where, at the moment when

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[82] Rothstein, *supra*, note 75 at 338.

[83] *Bragdon*, 524 U.S. at 637. *See* Clegg, *supra*, note 70 at 411; see also Rothstein, *supra,* note 75 at 341-42, distinguishing between expressed, or symptomatic, and unexpressed, or asymptomatic, genetic disorders.

[84] Miller, *supra*, note 75 at 243-44.

[85] U.S. EEOC, Notice No. 915.002, Policy Guidance on Executive Order 13,145, Prohibiting Discrimination in Federal Employment Based on Genetic Information (July 26, 2000) http://www.eeoc.gov/policy/docs/qanda-genetic.html Although this guidance addresses the Rehabilitation Act, the same definition of impairment is applied under the ADA.

[86] Rothstein, *supra*, note 75 at 348-51.

[87] 527 U.S. 471 (1999).

[88] 527 U.S. 516 (1999).

[89] 527 U.S. 555 (1999).

the alleged discrimination is held to have occurred, an impairment substantially limits a major life activity. If a person uses a mitigating device or takes medicines that alleviate symptoms and the individual thus is not at that moment substantially limited in a major life activity, the ADA does not apply. Moreover, the Court also held that each case must be assessed independently.[90] EEOC guidelines stating that persons be judged in their uncorrected or unmitigated state ran directly counter to this mandated individualized inquiry: "A person whose physical or mental impairment is corrected by medication or other measures does not have an impairment that presently 'substantially limits' a major life activity."[91] The Court was careful to note that use of a mitigating device or medication did not mean that the individual no longer had an impairment, only that the impairment did not rise to the level of an ADA-covered disability.[92]

In concluding that not all health conditions should be considered as disabilities, the Court noted that the ADA would cover well over 100 million individuals if mitigated health conditions were included. The Court compared that number to the estimated 43 million individuals with substantially limiting disabilities referred to in the preamble of the statute and its legislative history.[93] And as one legal scholar commented, if the ADA were deemed to cover everyone with a genetic predisposition to an impairment, its coverage would expand to encompass everyone—282 million people and counting.[94] The courts are not likely to reach that conclusion.[95]

The Court in *Sutton* also addressed whether the plaintiffs' impairments fit within the "regarded as" prong of the ADA definition of disability. The Court concluded that this prong applies when a covered entity mistakenly believes a person has an impairment that substantially limits one or more major life activities or when the entity mistakenly believes that an actual, nonlimiting impairment substantially limits one or more major life activities.[96] In both situations, the entity must have misperceptions that often "result from stereotypic assumptions not truly indicative of...individual ability."[97] In *Sutton* the Court concluded that plaintiffs had not alleged and could not demonstrate that the airline's vision requirement reflected a belief that plaintiffs' vision substantially limited them in the major life activity of working as pilots.[98]

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[90] *Sutton,* 527 U.S., at 482-85.

[91] *Id.*

[92] *Id.*

[93] *Id.* at 484-87.

[94] Cynthia Nance, Paul Miller, & Mark Rothstein, Discrimination in Employment on the Basis of Genetics: Proceedings of the 2002 Annual Meeting, Association of American Law Schools Section on Employment Discrimination Law, *6 Empl. Rts. & Employ. Pol'y J. 57, 75-76 (2002)* (view of Professor Rothstein expressed in panel discussion); Mark A. Rothstein, Genetics and the Work Force of the Next Hundred Years, *2000 Colum. Bus. L. Rev. 371, 386-87.*

[95] *Id.*

[96] *Sutton,* 527 U.S. at 489.

[97] *Id.*

[98] *Id.* at 490-94.

The Court in *Sutton* also cast doubt on what deference courts should give the EEOC guidance on the definition of disability. The Court stated:

> No agency, however, has been given authority to issue regulations implementing the generally applicable provisions of the ADA, see §§ 12101-12102, which fall outside Titles I-V. Most notably, no agency has been delegated authority to interpret the term "disability." § 12102(2).... The agencies have also issued interpretative guidelines to aid in the implementation of their regulations.... Although the parties dispute the persuasive force of these interpretative guidelines, we have no need in this case to decide what deference is due.[99]

Clearly, the Court in *Sutton* did not consider the EEOC definition of "disability" to have any binding effect, and it easily brushed the definition aside.[100]

Following *Sutton*, the Court further narrowed the scope of the ADA in *Toyota v. Williams*.[101] Here, the Court focused on the terms "substantially" and "major" in the phrase "substantially limits a major life activity." Referring to a dictionary, the Court stated that "substantially" means "to a large degree" and does not include "minor" restrictions; "major" means "important." An impairment rises to the level of a "disability" only if it "prevents or severely restricts the individual from doing activities that are of central importance to most people's daily lives" and is "permanent or long-term."[102] It is notable that the Court, in parsing the definition of these terms, expresses them in the present tense; as stated originally in *Sutton*, a person must be substantially limited in a major life activity at the time of the alleged discriminatory action.

Reading *Bragdon* in light of the decisions in *Sutton*, *Williams*, and other subsequent cases raises questions about whether a genetic predisposition to a disease or disorder would be considered a disability. At the very least, a court is unlikely to find that genetic predispositions generally constitute disabilities in all situations.[103] Furthermore, under the test established in *Sutton* for the third, "regarded as" prong of the definition of disability, it is unlikely that a court would find that an employer making a decision today based on an individual's genetic predisposition to a disease or disorder in the future would be considering that person presently impaired; rather, that employer would be discriminating against a nondisabled individual who might develop a future

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[99] *Id.* at 479-80.

[100] See also, *Albertson's Inc. v. Kirkingburg*, 527 U.S. 555 (1999).

[101] 534 U.S. 184 (2002).

[102] *Id.* at 196-98.

[103] See Rothstein, *supra*, note 75 at 350.

impairment.[104] Even if the courts were to uphold the EEOC's interpretation of the ADA, carriers of recessive genes would not appear to be protected.[105]

B. Access to Genetic Information

Another significant weakness in the ADA is that it does not prevent employers from asking for genetic information or requiring that certain individuals take genetic tests. Nothing prevents employers from obtaining genetic information from an applicant once the employer has made a conditional offer of employment. Rather, it only limits the employer's use of the information.[106] Under the ADA, an employer may require a medical examination after an offer of employment has been made—there is no limit as to what an employer may ask or what types of tests it may conduct—and condition its offer on the outcome of the examination.[107] This effectively permits an employer to learn the medical history of a prospective employee and then refuse to hire the person, if the employer believes that the hiring could be costly in terms of attendance, productivity, or insurance.[108]

No court has yet addressed the scope of the ADA with respect to genetic information or discrimination. In May 2002, the EEOC settled its first court action challenging an employer's use of genetic testing. The EEOC had sought a preliminary injunction under the ADA against Burlington Northern Santa Fe Railroad's nationwide policy of requiring employees who submitted claims of work-related carpal tunnel syndrome to provide blood samples for a genetic test for a chromosome 17 deletion. The Railroad claimed that this genetic anomaly causes carpal tunnel syndrome in rare cases. After the Commission filed suit, Burlington Northern agreed to stop requiring genetic tests, using genetic information related to its employees, or disclosing that information to the public. The Railroad also agreed to pay $2.2 million to the employees who were tested or asked to take the test.[109] It could be argued that this case demonstrates the

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[104] Jennifer Chorpening, Genetic Disability: A Modest Proposal to Modify the ADA to Protect Against Some Forms of Genetic Discrimination *82 N.C. L. Rev. 1441, 1453-54 (2004).*

[105] Testimony of Dr. Francis Collins, Advances in Genetic Research and Technologies: Challenges for Public Policy: Hearing Before the Senate Comm. on Labor and Human Res., 104th Cong. 2, 15 (1966). Some genetic diseases are recessive, i.e., manifested only if both parents contribute an allele to the offspring. A carrier of a recessive disease gene does not express the disease, but may pass the recessive disease gene on to his or her offspring. In this case, the offspring would only manifest the disease if he received a second recessive disease gene from his other parent. Any discrimination by an employer against a carrier of a recessive gene would seem to be based upon a misunderstanding of the likelihood that the employee or his or her offspring would express the disease.

[106] Pagnattaro, *supra,* note 7 at 165. Incumbent employees enjoy somewhat broader protection from medical examinations that seek disclosure of genetic information. In that context, an employer "shall not require a medical examination and shall not make inquiries of an employee as to whether such employee is an individual with a disability or as to the nature or severity of the disability, unless such examination or inquiry is shown to be job-related and consistent with business necessity." 42 U.S.C. 12112(d)(4)(A).

[107] 42 U.S.C. § 12112(d)(3).

[108] Pagnattaro, *supra,* note 7 at 165.

[109] *EEOC v. Burlington Northern Santa Fe Railroad,* Civ. No. 01-4013 MWB (N.D. Ia. April 23, 2001) (Agreed Order).

sufficiency of the ADA protections against genetic discrimination. But, as the facts indicate, the parties settled this case, and no court ever addressed the merits of the EEOC's allegations.

Despite its success in using the ADA to protect against genetic discrimination in the Burlington Northern case, the EEOC supports legislation prohibiting discrimination based on genetic information. The EEOC has noted that the ADA does not explicitly address genetic discrimination and that it is unclear whether the courts would construe the ADA to provide adequate protection against such discrimination.[110] Legal commentators also have questioned whether the ADA provides adequate protection against genetic discrimination, particularly in light of the recent court trends, noted above, narrowing the scope of the ADA's protections.[111]

C. Employer Defenses to Claims of Genetic Discrimination

Employers may successfully raise several defenses against allegations of genetic discrimination.[112] In addition to the defense that a genetic predisposition does not fall within the definition of "disability" (see discussion above), these defenses include a lack of qualification for the position, because the needed accommodation would create an undue hardship for the employer[113] and the employment decisions were based on factors other than those alleged.[114] The application of the defense that the disabled worker poses a direct threat to self or others[115] to a genetic predisposition is uncertain, because at least one court has held that there must be a high probability of substantial harm.[116] However, one scholarly article has concluded that the direct threat defense is likely to be successful in genetic predisposition cases.[117]

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[110] Testimony of Cari M. Dominguez, Chair, U.S. Equal Employment Opportunity Commission, before the Senate Committee on Health, Education, Labor and Pensions (HELP), U.S. Senate Hearing on Protecting Against Genetic Discrimination: The Limits of Existing Laws (Feb. 13, 2002). http://www.eeoc.gov/abouteeoc/coordination/dominguezspeech.html Testimony of Paul Steven Miller, Commissioner, U.S. Equal Employment Opportunity Commission before the Senate HELP Committee, U.S. Senate Hearing on Genetic Information in the Workplace (July 20, 2000). http://www.genome.gov/10001390

[111] Ellis, *supra,* note 60 at 1083-87; Pagnattaro, *supra,* note 7 at 156, 158-163; Nance, Miller, & Rothstein, *supra*, note 90 at 75-76 (view of Professor Rothstein expressed in panel discussion); Rothstein, *supra*, note 90 at 386-87.

[112] Anita Silvers & Michael Ashley Stein, Human Rights and Genetic Discrimination: Protecting Genomics' Promise for Public Health, *31 J. L. Med. & Ethics 377, 379-80 (2003).*

[113] *Id.*

[114] *Id.* at 380.

[115] In *Chevron U.S.A. Inc. v. Echazabal,* 536 U.S. 73 (2002) the United States Supreme Court upheld the EEOC regulation expanding the direct threat defense to authorize exclusion of an employee whose work could endanger his own health.

[116] *Simms v. City of New York,* 160 F. Supp. 2d 398, 407 (E.D.N.Y. 2001).

[117] Silvers & Stein, *supra*, note 108 at 380.

Because the ADA does not expressly include genetic information and no court has addressed a case of genetic discrimination under the ADA, it is unknown whether the statute may be interpreted to prohibit genetic-based employment discrimination.[118] It seems clear, however, that the ADA is limited in the manner and extent of its coverage and that the prevailing trend in the Supreme Court and lower Federal courts is to interpret narrowly the coverage of the ADA.[119]

II. Title VII of the Civil Rights Act of 1964

Title VII of the Civil Rights Act of 1964 prohibits employment discrimination on the basis of race, color, religion, sex, and national origin.[120] Title VII covers all private employers having 15 or more workers, labor organizations, employment agencies, and Federal, State, and municipal government employers.[121] The language of the statute does not refer to protection against genetic discrimination, but Title VII may offer some protection against discrimination on the basis of a person's genetic makeup when that discrimination disproportionately affects individuals belonging to one of the protected groups.[122] For example, an employer refusing to hire carriers of the genetic mutation for Tay-Sachs disease arguably would be discriminating against persons with an Eastern European Jewish ethnic background—a prohibited disparate impact on the basis of national or ethnic origin.[123]

A violation of Title VII may also be found on the basis of who is selected for testing. In *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*,[124] present and former employees of the laboratory alleged that the testing of only black employees for sickle cell disease and the testing of women for pregnancy violated Title VII. The court of appeals overturned the district court's dismissal of these claims, finding that the singling out of black and female employees for additional nonconsensual testing invaded the privacy of those employees on the basis of race, sex, and pregnancy.[125] If every applicant or employee received the same genetic test, an individual would have to prove that the test had a discriminatory effect on her or him as a

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[118] Katherine A. Hathaway, Federal Genetic Nondiscrimination Legislation: The New "Right" and Race to Protect DNA at the Local, State, and Federal Level, *52 Cath. U. L. Rev. 133, 141 (2002).*

[119] See Congressional Research Service, Genetic Information: Legal Issues Relating to Discrimination and Privacy, Report For Congress, RL30006, July 19, 2001, p.11, at http://www.cnie.org/nle/crsreports/science/st-55.pdf The CRS Report concludes that: "the reasoning used in the Court's recent decisions appears to make it unlikely that an ADA claim based on genetic discrimination would be successful."

[120] 42 U.S.C. 2000e - e17.

[121] 42 U.S.C. 2000e(b).

[122] S. Rep. 108-122, *supra*; note 58 at 11; Jared A. Feldman & Richard J. Katz, Genetic Testing & Discrimination in Employment: Recommending a Uniform Statutory Approach, *19 Hofstra Lab. & Emp. L. J. 389, 405-06 (2002).*

[123] *Id.*

[124] 135 F.3d 1260 (9th Cir. 1998).

[125] *Id.* at 1271-73.

member of a protected class (the Tay-Sachs example, above).[126] Because most genetic disorders do not disproportionately affect a protected class, Title VII would not adequately protect employees from genetic discrimination.[127]

III. Constitutional Protections for Genetic Information and Against Genetic Testing

A. Right to Privacy in Medical Information

In *Whalen v. Roe*,[128] the Supreme Court recognized an individual's constitutional right to privacy in his or her medical information but concluded that the interest of the State outweighed that interest. The Court held that a New York statute requiring the State to record the names and addresses of prescription drug users was constitutional because the interest of the State in collecting the information outweighed the interests of the individuals in keeping the information private.[129] Because genetic information is especially, and some say uniquely, personal and has implications not only for the individual but also for his or her family, it has been argued that genetic information deserves more protection than other forms of medical information.[130] However, as is the case for all of the constitutional protections discussed in this section, the extent of that protection is limited by (1) the fact that the Constitution applies only to government action and does not reach private employers and (2) the courts' weighing of individuals' rights under the Constitution against the public health or other interests of the government in taking the action.[131]

Although the Supreme Court has not specifically considered the issue of privacy rights in genetic information, the United States Court of Appeals for the Ninth Circuit has. In *Norman Bloodsaw v. Lawrence Berkeley Laboratory*,[132] a facility jointly operated by State and Federal agencies performed medical tests for syphilis, sickle cell trait, and pregnancy during preplacement examinations without informing employees of either the testing or the results. The employees sued, claiming, among other things, that those tests violated their right to privacy under the United States Constitution. The Court of Appeals reversed the district court's dismissal of that claim, concluding that "One can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up."[133] The Court found

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[126] Feldman & Katz, *supra*, note 118 at 406.

[127] S. Rep. 108-122 and Feldman & Katz, *supra*, note 118.

[128] 429 U.S. 589 (1977).

[129] *Id.* at 600.

[130] Melinda B. Kaufmann, Genetic Discrimination in the Workplace: An Overview of Existing Protections, *30 Loy. U. Chi. L. J. 393, 430 (1999).*

[131] Miller, *supra*, note 75 at 251.

[132] Note 124, *supra*.

[133] 135 F.3d. at 1268-70.

that the tests implicated rights protected under both the Fourth Amendment to the United States Constitution and the Due Process Clause of the Fifth and Fourteenth Amendments.[134] Specifically, the Court found that the carrying of the sickle cell trait pertains to sensitive information about family history and reproductive decision making, and thus, it and the other conditions tested for were aspects of one's health in which one has the highest expectation of privacy.[135] The Court of Appeals rejected the district court's ruling that the intrusions were de minimus in light of the overlap between the tests and a medical questionnaire the employees completed and the employees' submission to the preplacement medical examination at which the blood used in the test was drawn.[136] The Court of Appeals remanded the case for trial on the issues of fact with respect to whether reasonable persons in plaintiffs' position would have had reason to know the tests were being performed as part of the preplacement medical exam (and thus whether they had a reasonable expectation of privacy) and whether defendants had any interest in obtaining the information.[137]

B. Fourth Amendment Protections

Although the Fourth Amendment's protection against unreasonable searches and seizures is generally invoked in criminal proceedings, it has been applied to noncriminal searches as well.[138] The court in the *Norman Bloodsaw* case (discussed above) specifically relied on the Fourth Amendment, pointing out that the Supreme Court has recognized that while the taking of a bodily fluid sample implicates one's privacy interests, the subsequent analysis of the sample to obtain physiological data is a further intrusion on the tested employee's privacy interests.[139] It has been suggested that the government would be hard-pressed to articulate a legitimate need for a genetic test that "reveals the deepest secrets of an individual's past, present, and projected future including those of his or her family,"[140] but if the test were limited to a genetic marker for susceptibility to a disease or condition that would raise safety concerns, the courts may have less difficulty in finding a legitimate governmental need.[141]

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[134] *Id.*

[135] *Id.*

[136] *Id.* at 1266-70.

[137] *Id.* at 1266-1271, 1275.

[138] Kaufmann, *supra,* note 126 at 431.

[139] 135 F.3d at 1270 n.13, citing *Skinner v. Railway Labor Executives' Ass'n*, 489 U.S. 489 (1989).

[140] Kaufmann, *supra*, note 126 at 433.

[141] Kaufmann, *supra,* note 126 at 431-33 (discussion of the balancing test for mandatory HIV testing at the workplace and for drug testing at hazardous work sites).

IV. Protections for Federal Employees

In addition to the constitutional protections discussed above, employees of the Federal Government are protected from genetic discrimination by Executive Order 13,145 issued on February 8, 2000.[142] The Executive Order prohibits departments and agencies of the Executive Branch from using "protected genetic information," defined as information about the genetic tests of an individual or his or her family members and information about the occurrence of a disease or medical condition in the individual's family members, to discharge, not hire, or otherwise discriminate against any applicant or employee with respect to the compensation, terms, conditions, or privileges of employment.[143] An agency or department may request or require protected genetic information if the request is consistent with the Rehabilitation Act and it is used only to diagnose a current disease that could prevent the employee from performing the essential functions of the position.[144] Genetic monitoring of the biological effects of toxic substances in the workplace is permitted if an employee has given knowing and voluntary consent and if the employer learns of the test results only in aggregate terms that do not identify employees.[145] The Executive Order does not apply to the private sector, but it may serve as a model for legislation.[146]

CONCLUSION

Currently there are no Federal laws that directly and comprehensively address the issues raised by the use of genetic information.[147] As discussed in this analysis, there are laws and court decisions that address parts of these issues, but they leave substantial gaps in coverage and offer questionable and inconsistent safeguards at best.[148] Because there has not yet been a leading court decision on genetic discrimination, we cannot know the full extent of the gaps in current law.[149]

As noted above, however, current Federal nondiscrimination in health insurance laws do not apply to individual health insurance policies, and a group health insurer may request, purchase, or otherwise obtain genetic information about an individual or require that individual to submit to a genetic test as a condition of coverage and, on the basis of the information obtained, charge all members of the group higher premiums. Title III of the ADA, which prohibits discrimination

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[142] 65 Fed. Reg. 6877 (Feb. 8, 2000).

[143] *Id.*

[144] *Id.*

[145] *Id.*

[146] Ellis, *supra*, note 60 at 1087-88.

[147] Congressional Research Service, *supra*, note 115 at 4.

[148] Hathaway, *supra*, note 114 at 138.

[149] *Id.*

on the basis of disability in the enjoyment of the goods and services of places of public accommodation, has been held not to apply to insurance policies in five of the seven United States Courts of Appeal that have addressed the issue. Forty-seven states and the District of Columbia restrict the use of genetic information to determine health insurance rates or eligibility in group or individual health plans or both. However, State laws are not uniform or comprehensive, and under ERISA, self-insured employee benefit plans are generally exempt from State regulation.

There is no Federal statute that directly protects against genetic discrimination in employment, but some protection may be provided through the ADA. The EEOC takes the position that the ADA prohibits genetic discrimination and successfully settled its first court action challenging an employer's use of genetic testing to screen employees. It is apparent, however, that the Supreme Court is moving toward a more narrow interpretation of the ADA and that there are a number of potentially successful defenses to the application of the ADA to broadly prohibit genetic discrimination. This state of uncertainty may be as potentially harmful to employers as it is to employees.[150] Title VII of the Civil Rights Act of 1964 offers some protection against genetic discrimination, but only when discrimination on the basis of a person's genetic makeup disproportionately affects the person on the basis of race, color, religion, sex, or national origin, such as would be the case if the employer refused to hire carriers of the genetic mutation for sickle cell disease.

The constitutional right to privacy of medical information has been applied to genetic information, and the Fourth Amendment protection against unreasonable searches and seizures has been applied to limit genetic testing. However, these constitutional protections are limited to governmental action, and it is well established that the courts will weigh the encroachment on individual rights against the public health or other interests of the government in taking the action that results in that encroachment.

In sum, individuals who encounter genetic discrimination cannot be said to lack any avenues for relief under current law. However, many legal commentators have concluded that existing avenues for relief are uncertain and likely to lead to costly litigation and that current law does not adequately protect against discrimination based on genetic predisposition.[151]

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[150] See Chorpening, *supra*, note 100 at 1460.

[151] See Chorpening, *supra*, note 100 at 1468.