

Report for Congress

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Genetic Information: Legal Issues Relating to Discrimination and Privacy

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Summary

On June 26, 2000, in a special ceremony at the White House, the completion of the “rough draft” of the human genome was announced. This milestone, which has been compared to the discoveries of Galileo, and other advances in genetics have created novel legal issues relating to genetic information. The Human Genome Project, with its goal of producing detailed maps of the 23 pairs of human chromosomes and sequencing the three billion nucleotide bases that make up the human genome, has been instrumental in the identification of genes implicated in various diseases including glaucoma, colon cancer, and cystic fibrosis. With the identification of these genes comes the hope of genetic therapies to cure disease but this scientific accomplishment is not without potential problems. For instance the presence of a cancer causing gene may indicate a predisposition but does not guarantee that the person will contract the disease: How should an employer or insurer respond? The ethical, social and legal implications of these technological advances have been the subject of significant scrutiny and concern.

The legal implications of such information have been mainly on the state level but there are some relevant Federal statutes. The Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, is the first federal law to specifically address discrimination and insurance issues relating to genetic discrimination. Congress has considered several bills concerning genetics during the past several Congresses but has not enacted comprehensive legislation. However, on May 21, 2003, the Senate Health, Education, Labor and Pensions (HELP) Committee unanimously passed a manager’s substitute amendment to S. 1053 which is designed to protect against genetic discrimination (Press Release, HELP Committee, HELP Cmte. Passes Bipartisan Genetic Anti-Discrimination Legislation, May 21, 2003). This report discusses current federal law, state statutes, and legislation. It will be updated as needed.

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Genetic Information: Legal Issues Relating to Discrimination and Privacy

Background

On June 26, 2000, in a special ceremony at the White House, the completion of the “rough draft” of sequence of the human genome was announced. More specifically, the scientists involved in the Human Genome Project (HGP)¹ reported that this rough draft consists of overlapping fragments covering 97% of the human genome, and a sequencing of 85% of the human genome.² By the end of 2003 the full sequence should be completed.³ These rapid advances provide powerful tools for information about the causes, and potentially the cures, for diseases such as diabetes, heart disease, Parkinson’s disease, bipolar illness, and asthma.

In congressional testimony Dr. Francis Collins, the Director of the National Human Genome Research Institute, described the dramatic progress of the Human Genome Project and stated that “these revelations hold within them the promise of a true transformation of medical practice. Quite possibly before the end of the first decade of this new millennium, each of us may be able to learn our individual susceptibilities to common disorders, in some cases allowing the design of a program of effective individualized preventive medicine focused on lifestyle changes, diet and medical surveillance to keep us healthy....These same discoveries about genetics likely will lead us to predict who will respond most effectively to a particular drug therapy, and who may suffer a side effect and out to avoid that particular drug.”⁴

¹ The Human Genome Project, begun in 1990, is a 13 year effort coordinated by the U.S. Department of Energy and the National Institutes of Health to identify all the estimated 80,000 genes in human DNA and to determine the sequences of the 3 billion chemical bases that make up human DNA, store this information in data bases, develop tools for data analysis, and address the ethical, legal, and social issues (ELSI) that may arise from the project. The Human Genome Project is funded through the Department of Energy and the National Institutes of Health. For more detailed information see “The National Human Genome Research Institute,” [<http://www.nhgri.nih.gov>] and “Human Genome Research,” [http://www.er.doe.gov/production/ober/hug_top.html]

² “International Human Genome Sequencing Consortium Announces ‘Working Draft’ of Human Genome,” [http://www.nhgri.nih.gov/NEWS/sequencing_consortium.html]

³ http://www.er.doe.gov/production/ober/hug_top.html

⁴ Testimony of Francis S. Collins, Director, National Human Genome Research Institute, National Institutes of Health, Before the Senate Health, Education, Labor and Pensions Committee (July 20, 2000).

The first apparently successful genetic therapy has been recently reported⁵ and in the not too distant future, the benefits of genetic therapy have been seen by some as little short of miraculous with potential cures of major diseases such as heart disease, and cancer, and Alzheimer's. However, there have been numerous ineffective efforts at gene therapy and at Senate hearings, held following the death of a patient involved in gene therapy, Senator Frist stated that gene therapy holds "great promise, but because gene therapy is an experimental, high risk procedure, there is a need for vigilant oversight to ensure patient safety."⁶

These scientific advances in genetics are not without other potential problems. The ethical, social and legal implications of genetic research have been the subject of significant scrutiny and a portion of the funds for the Human Genome Project are set aside for use in analyzing these issues.⁷ As scientific knowledge about genetics becomes increasingly widespread, numerous researchers and commentators, including Dr. Francis Collins, have expressed concerns about how this information is to be used.⁸ In recent congressional testimony, Dr. Collins stated: "while genetic information and genetic technology hold great promise for improving human health, they can also be used in ways that are fundamentally unjust. Genetic information can be used as the basis for insidious discrimination....The misuse of genetic information has the potential to be a very serious problem, both in terms of people's access to employment and health insurance and the continued ability to undertake important genetic research."⁹

This concern has encompassed fears of discrimination in many aspects of life, including employment, and health and life insurance. A study on discrimination found that a number of institutions, including health and life insurance companies, health care providers, blood banks, adoption agencies, the military and schools, were reported to have engaged in genetic discrimination against asymptomatic

⁵ Rick Weiss, "Genetic Therapy Apparently Cures 2," *The Washington Post* A-1 (April 28, 2000).

⁶ Testimony of Bill Frist United States Senator Tennessee Before the Senate Committee on Health, Education, Labor and Pensions Subcommittee on Public Health, Gene Therapy: Is there Oversight for Patient Safety?" (February 2, 2000).

⁷ The group working on these issues is referred to as the Ethical, Legal and Social Implications (ELSI) program. See [<http://www.genome.gov/page.cfm?pageID=10001618>].

⁸ Testimony by Dr. Francis Collins, Director, National Center for Human Genome Research, Before the Senate Committee on Labor and Human Resources (March 6, 1996). See also, Hudson, Rothenberg, Andrews, Kahn, and Collins, "Genetic Discrimination and Health Insurance: An Urgent Need for Reform," 270 *Science* 391 (Oct. 20, 1995); Annas, Glantz and Roche, "Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations," 23 *J. of Law, Medicine and Ethics* 360 (1995); Gostin, "Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers," 17 *Am. J. of Law & Med.* 109 (1991); Rothstein, Mark, *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997).

⁹ Testimony of Francis S. Collins, Director, National Human Genome Research Institute, National Institutes of Health, Before the Senate Health, Education, Labor and Pensions Committee (July 20, 2000).

individuals.¹⁰ The discriminatory practices included allegedly treating a genetic diagnosis as a preexisting condition for insurance purposes, refusal by an adoption agency to allow a woman at risk for Huntington's disease to adopt based on the woman's genetic risk, and termination from employment after disclosure of a risk of Huntington's disease.¹¹ Similarly, another study reported that twenty-two percent of the respondents indicated that they or a family member were refused health insurance as a result of a genetic condition.¹² This study was strongly criticized by the Health Insurance Association of America (HIAA) which has argued that there is no evidence showing that insurers engage in genetic discrimination and that federal legislation to prohibit discrimination based on genetic information is unnecessary.¹³ Ronald Adler, President of Laurdan Associates, a human resource management consulting firm, has testified that generally employers do not currently seek employees' genetic information and do not plan to do so. However, he noted that "federal legislation may still be warranted" to help allay fears that may prevent individuals from undergoing potentially life-saving genetic tests or participate in genetic research.¹⁴

A joint report by the Department of Labor, the Department of Health and Human Services, the Equal Employment Opportunity Commission and the Department of Justice summarized the various studies on discrimination based on genetic information and argued for the enactment of federal legislation. The report stated that "genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy and unlikely to develop disease or where the genetic condition has no effect on the ability to perform work" and that "because an individual's genetic information has implications for his or her family members and future generations, misuse of genetic information could have intergenerational effects that are far broader than any individual incident of misuse."¹⁵ Concluding that existing protections are minimal, the report went on to

¹⁰ Geller, Alper, Billings, Barash, Beckwith, and Natowicz, "Individual, Family, and Societal Dimensions of Genetic Discrimination: A Case Study Analysis," 2 *Science and Engineering Ethics* 71 (1996). The study has been criticized by the insurance industry as relying on anecdotal information. See American Council of Life Insurance, "Statement Regarding the Council for Responsible Genetics 'Study' on Genetic Discrimination" (April 11, 1996).

¹¹ *Id.*

¹² Lapham, E. Virginia, Kozma, Chahira, Weiss, Joan O., "Genetic Discrimination: Perspectives of Consumers," 274 *Science* 621 (October 25, 1996).

¹³ "Testimony of the HIAA on Genetic Testing," Before the Senate Committee on Labor and Human Resources, 105th Cong., 2d Sess. (May 21, 1998).

¹⁴ "Testimony of Ronald L. Adler, President of Laurdan Associates, Inc.," "Protecting Against Genetic Discrimination: The Limits of Existing Laws," Before the Senate Committee on Health, Education, Labor and Pensions, 107th Cong., 2d Sess. (Feb. 13, 2002), reprinted at [<http://labor.senate.gov/Hearings-2002/feb2002/021302wit/021302wit.htm>].

¹⁵ Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice, "Genetic Information and the Workplace," [<http://www.dol.gov/asp/programs/history/herman/reports/genetics.htm>] 2-3 (January 20,

call for the enactment of legislation which states that (1) employers should not require or request that employees or potential employees take a genetic test or provide genetic information as a condition of employment or benefits, (2) employers should not use genetic information to discriminate against, limit, segregate, or classify employees, and (3) employers should not obtain or disclose genetic information about employees or potential employees under most circumstances.¹⁶ According to the Labor Department report, employers should be able to (1) use genetic information for monitoring for the effects of a particular substance in the workplace under certain circumstances, and (2) disclose genetic information for research and other purposes with the written, informed consent of the individuals. In addition, the report states that the statutory authority of federal agencies or contractors to promulgate regulations, enforce workplace safety and health laws, or conduct occupational or other health research should not be limited.¹⁷

The National Council on Disability (NCD), an independent federal agency that advises the President and Congress on issues affecting individuals with disabilities, published a position paper arguing for the enactment of federal legislation prohibiting genetic discrimination on March 4, 2002. The NCD argues that recent advances in genetic research have brought an increasing potential for genetic discrimination, that genetic discrimination is a historical and current reality, that genetic discrimination undermines the purposes of genetic research and testing, that genetic test information has little value for purposes of making employment decisions and insurance decisions, and that existing laws are insufficient to protect individuals from genetic discrimination.¹⁸

President Bush has also made the prohibition of genetic discrimination one of the key components of the President's health care reform agenda. The President has indicated his support of "reasonable legislation that will make genetic discrimination illegal."¹⁹

It should be emphasized that legal issues relating to genetics may vary depending on whether insurance, employment or other types of discrimination, or medical research are involved. Approaches to addressing the issues raised in these contexts vary from taking no legislative action, addressing certain specific concerns (as was done in the Health Insurance Portability and Accountability Act), or more far

¹⁵ (...continued)
1998).

¹⁶ Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice, "Genetic Information and the Workplace," [http://www.dol.gov/asp/programs/history/herman/reports/genetics.htm] at 7 (January 20, 1998).

¹⁷ Id.

¹⁸ National Council on Disability, "Position Paper on Genetic Discrimination Legislation" [http://www.ncd.gov/newsroom/publications/geneticdiscrimination_positionpaper.html]

¹⁹ "Key Components of the President's Health Care Reform Agenda," [www.whitehouse.gov/news/releases/2002/03/20020301-1.html].

reaching approaches such as comprehensive legislation on genetics or legislation focused on all medical records, including genetics.

Generally legal issues raised regarding genetics have been based on two main concepts: privacy and discrimination. The privacy interests of an individual in his or her genetic information have been seen as significant and protecting these interests is seen as making discriminatory actions based on this information less likely. However, another approach would be to prohibit this potential misuse of the information by prohibiting discrimination. Some statutes, like the Americans with Disabilities Act (ADA), 42 U.S.C. §§ 12101 *et seq.*, take a two-pronged approach to similar issues regarding medical information about disabilities by both protecting the confidentiality of the information and by prohibiting discriminatory acts.

Currently there are no federal laws that directly and comprehensively address the issues raised by the use of genetic information. There are, however, a few laws that address parts of these issues but the only federal law that directly addresses the issue of discrimination based on genetic information is the Health Insurance Portability and Accountability Act. On February 8, 2000, President Clinton issued an executive order prohibiting discrimination against federal employees based on protected genetic information. On December 20, 2000, the Department of Health and Human Services issued final regulations on medical privacy which are not specific to genetics but cover all personal health information.²⁰ This rule went into effect on April 14, 2001 but was amended in 2002.²¹ In addition, many states have enacted laws which vary widely in their approaches to genetic information.

The Health Insurance Portability and Accountability Act of 1996

P.L. 104-191, the Health Insurance Portability and Accountability Act of 1996²², has been hailed as taking “important steps toward banning genetic discrimination in health insurance” but has also been criticized as not going far enough.²³ The Act prohibits a group health plan or issuer of a group health plan from using genetic information to establish rules for eligibility or continued eligibility and provides that genetic information shall not be treated as a preexisting condition in the absence of the diagnosis of the condition related to such information. It also prohibits a group health plan or issuer of a group health plan from using genetic information in setting a premium contribution. These protections apply to individuals within the group plans; they do not apply to the acceptance of the whole group or to the premiums set

²⁰ 65 Fed. Reg. 82460 (Dec. 20, 2000).

²¹ See *infra* pp. 14-16 for a more detailed discussion.

²² For a general discussion of this Act see, Hinda R. Chaikind, Jean Hearne, Bob Lyke, and Stephen Redhead, *The Health Insurance Portability and Accountability Act (HIPAA) of 1996: Overview and Guidance on Frequently Asked Questions*, CRS Report RL31634.

²³ Statement of Rep. Louise Slaughter Before the House Science Subcommittee on Technology, Hearing on Technological Advance in Genetic Testing: Implications for the Future, September 17, 1996.

for the group. The Act would not prohibit group health plans or issuers of plans (i.e., insurers) from requiring or requesting genetic testing, does not require them to obtain authorization before disclosing genetic information, and does not prevent them from excluding all coverage for a particular condition or imposing lifetime caps on all benefits or on specific benefits. In addition, this Act does not address the issues of the use of genetic information in contexts other than health insurance such as employment.²⁴

Executive Order

On February 9, 2000, President Clinton signed Executive Order 13145 prohibiting genetic discrimination against employees in federal executive departments and agencies. In announcing the executive order at a meeting of the American Association for the Advancement of Science, the President stated that “This extraordinary march of human understanding imposes on us a profound responsibility to make sure that the age of discovery can continue to reflect our most cherished values.”²⁵ Many commentators lauded the executive order, and quoted with approval its description as “preventive policy making— to put in place the kind of protections that the public needs and deserves before we find ourselves in a needless crisis situation.”²⁶ However, it has also been criticized both on a philosophical level²⁷ and in the details of its coverage.²⁸ The EEOC has issued guidance on the executive order.²⁹

The executive order defines “protected genetic information” as “(A) information about an individual’s genetic tests; (B) information about the genetic tests of an

²⁴ It should also be noted the HIPAA contains certain requirements regarding the standardization of claims that raise potential privacy issues. HIPAA addressed these issues by requiring either congressional action or regulatory action to protect privacy. A more detailed discussion of this issue is contained in the section on privacy.

²⁵ “President’s Order Bars Discrimination Based on Genetics,” *Investor’s Business Daily A9* (February 9, 2000).

²⁶ Wendy R. Uhlmann, “When Genes are Decoded, Who Should See the Results?; Every one of us at Risk,” *The New York Times F7* (February 29, 2000).

²⁷ Michael Kinsley, editor of *Slate*, an online magazine, observed that “genetic discrimination is universal, inevitable and, in some ways, essential....Practice, practice will get you to Carnegie Hall, but only if you’ve been born on the right bus....The world would be a poorer place if it did not distinguish between me and Yo-Yo Ma in doling out opportunities to be a concert cellist.” Michael Kinsley, “Genetic Correctness,” *The Washington Post A29* (April 18, 2000).

²⁸ Mark A. Hall, a law professor at Wake Forest University, argues that the order’s prohibition of considering predictive genetic information would not allow for the screening of susceptibility to toxic exposure prior to working in such an environment and would not allow for the use of genetic predispositions to future conditions that could effect job performance. Mark A. Hall, “When Genes are Decoded, Who Should See the Results?; Many ‘Greatly Overestimate the Risk’,” *The Washington Post F7* (February 29, 2000).

²⁹ [<http://www.eeoc.gov/docs/guidance-genetic.html>]

individual's family members; or (C) information about the occurrence of a disease; or medical condition or disorder in family members of the individual." Current health status information would not be protected under this executive order unless it was derived from the information described above.

The executive order requires executive departments and agencies to implement the following nondiscrimination requirements:

- the employing entity shall not discharge, fail or refuse to hire, or otherwise discriminate against any employee because of protected genetic information or because of information about a request for or receipt of genetic services;
- the employing entity shall not limit, segregate or classify employees in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect that employee's status because of protected genetic information or because of information about a request for or receipt of genetic services;
- the employing entity shall not request, require, collect, or purchase protected genetic information with respect to an employee or information about a request for or receipt of genetic services;
- the employing entity shall not disclose protected genetic information with respect to an employee or information about a request for or receipt of genetic services with certain exceptions;
- the employing entity shall not maintain protected genetic information or information about a request for or receipt of genetic services in general personnel files. Such materials shall be treated as confidential medical records and kept separate from personnel files.

There are certain exceptions to these prohibitions. For example, the employing entity may request or require information if such current condition could prevent the applicant or employee from performing the essential functions of the job, or where it is to be used exclusively to determine whether further medical evaluation is needed to diagnose a current disease. Genetic monitoring of biological effects of toxic substances in the workplaces are permitted in certain circumstances.

The Americans with Disabilities Act

The Americans with Disabilities Act (ADA), 42 U.S.C. § 12101 *et seq.*, prohibits discrimination against an individual with a disability in employment, public services, public accommodations, and communications. The threshold issue in any ADA case is whether the individual alleging discrimination is an individual with a disability. The act defines the term disability with respect to an individual as having

“(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual, (B) a record of such an impairment; or (C) being regarded as having such an impairment.”³⁰ Although the statutory language of the ADA does not reference genetic traits, there was a discussion of the issue during congressional debate.³¹ So far there have been no judicial decisions but one case was brought by the EEOC and settled. In addition, Terri Seargent filed with the EEOC alleging genetic discrimination and received a determination on November 21, 2000 that the EEOC’s investigation supported her allegation of discrimination under the ADA.³²

EEOC Interpretation of the ADA Regarding Genetic Discrimination

The ADA has been interpreted by the Equal Employment Opportunity Commission (EEOC) as including genetic information relating to illness, disease, or other disorders.³³ The legislative history was cited by the EEOC in its guidance to the definition of disability for its compliance manual. In this guidance, the EEOC examined the definition of disability under the ADA, noting that the definition was composed of three prongs: disability means (1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual, (2) a record of such an impairment, or (3) being regarded as having such an impairment.³⁴

³⁰ 42 U.S.C. §12102.

³¹ Rep. Owens stated that “[t]hese protections of the ADA will also benefit individuals who are identified through genetic tests as being carriers of a disease-associated gene. There is a record of genetic discrimination against such individuals, most recently during sickle cell screening programs in the 1970’s. With the advent of new forms of genetic testing, it is even more critical that the protections of the ADA be in place. Under the ADA, such individuals may not be discriminated against simply because they may not be qualified for a job sometime in the future. The determination as to whether an individual is qualified must take place at the time of the employment decision, and may not be based on speculation regarding the future. Moreover, such individuals may not be discriminated against because they or their children might incur increased health care costs for the employer.” 136 Cong. Rec. H 4623 (daily ed. July 12, 1990) (remarks of Rep. Owens). Similarly, Rep. Edwards and Rep. Waxman also stated that individuals who are carriers of a disease-associated gene may not be discriminated against under the ADA. 136 Cong. Rec. H 4625 (daily ed. July 12, 1990) (Statement of Rep. Edwards); *Id.* at H 4627 (Statement of Rep. Waxman).

³² “Update on Terri Seargent’s Genetic Discrimination Case,” [http://www.alpha1.org/programs/newsmakers_seargent.htm]

³³ Equal Employment Opportunity Commission, Compliance Manual, vol. 2, section 902, order 915.002,902-45 (1995). It is also possible that title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., may provide some protection against certain kinds of genetic discrimination since an argument could be made that discrimination based on genetic disorders that are racially or ethnically based, such as sickle cell disease, is prohibited under title VII. However, there are relatively few genetic conditions that have a strong connection with a racial or ethnic group, thus limiting the scope of potential coverage.

³⁴ 42 U.S.C. §12102(2).

It was under the third prong that the EEOC determined that discrimination based on genetic information relating to illness, disease, or other disorders was prohibited.³⁵

Although this EEOC interpretation was widely heralded as a significant step for the protection of rights for individuals whose genes indicate an increased susceptibility to illness, disease or other disorders, it is limited in its application and may be even more limited after the recent Supreme Court decisions on the definition of disability.³⁶ However, the EEOC has not withdrawn this guidance and at recent Senate hearings, EEOC Commissioner Paul Miller stated that the ADA “can be interpreted to prohibit employment discrimination based on genetic information. However, the ADA does not explicitly address the issue and its protections are limited and uncertain.” In addition, Commissioner Miller observed that even if the ADA were found to cover genetic discrimination, the requirements of the ADA may not protect workers from all types of genetic discrimination. He stated, “for example, the ADA does not protect workers from requirements or requests to provide genetic information to their employers....In addition, once the applicant is hired, the employer may request that the employee take a medical exam, such as a genetic test, if the employer can demonstrate that the information from that test is job related and consistent with business necessity.”³⁷

³⁵ The EEOC gave the following example of its application of the third prong of the definition to genetic discrimination. 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.

³⁶ Prior to the Supreme Court’s decisions there were three major limitations on the EEOC interpretation. First, the ADA specifically excludes insurance from its coverage except that this exclusion “shall not be used as a subterfuge to evade the purposes of title I and III.” The exact parameters of this provision, especially as it relates to genetic information, are unclear although it would appear fair to say the nondiscrimination protections for individuals with certain genes would be considerably stronger in the employment context than when such individuals are being considered for insurance coverage. Second, the EEOC interpretation is part of guidance issued in its compliance manual. Specific prohibitions of discrimination in this area were not included in the statute and were also not part of the EEOC’s regulations. Even if a court gives deference to the guidance as indicative of the agency’s view of the statute, a court would not likely give such guidance the deference it would accord to statutory or regulatory language. In addition, even assuming the ADA was found to apply, it may not protect employees from having their employers have access to their genetic information. Although the ADA prohibits an employer from making medical inquiries prior to a job offer, the employer may obtain medical information in certain cases after the offer of employment has been made. Even if the prohibitions against discrimination in the ADA would apply, it would be difficult to prove that genetic information was the reason for discrimination. This raises issues relating to the privacy of genetic information which are beyond the scope of this memorandum.

³⁷ Statement of Commissioner Paul Steven Miller, U.S. Equal Employment Opportunity Commission, Before the Senate Committee on Health, Education, Labor and Pensions (July 20, 2000).

The first ADA case alleging genetic discrimination was filed with the EEOC by Terri Sargent. Ms. Sargent, whose situation was extensively discussed during Senate debate on genetic discrimination in the 106th Congress, had a promising career as a manager for a small insurance broker in North Carolina. She had positive performance evaluations but after medical tests determined that she had Alpha 1 Antitrypsin Deficiency, a condition that affects the lungs and liver, and she began taking expensive medication, she was terminated from her employment.³⁸ Ms. Sargent filed with the EEOC alleging genetic discrimination and received a determination on November 21, 2000 that the EEOC's investigation supported her allegation of discrimination under the ADA.³⁹

The EEOC settled its first court action challenging the use of workplace genetic testing under the ADA against Burlington Northern Santa Fe Railway (BNSF). The settlement, announced on April 18, 2001, ended genetic testing of employees who filed claims for work-related injuries based on carpal tunnel syndrome. EEOC Commissioner Paul Steven Miller stated "The Commission will continue to respond aggressively to any evidence that employers are asking for or using genetic tests in a manner that violates the ADA. Employers must understand that basing employment decisions on genetic testing is barred under the ADA's "regarded as" prong, as stated in EEOC's 1995 policy guidance on the definition of the term "disability." Moreover, genetic testing, as conducted in this case, also violates the ADA as an unlawful medical exam."⁴⁰

Supreme Court ADA Decisions

Although the combination of the ADA's legislative history and the EEOC's guidance has led commentators to argue that the ADA would cover genetic discrimination, the merit of these arguments has been uncertain since there have been no reported cases holding that the ADA prohibits genetic discrimination. This uncertainty has increased in light of recent Supreme Court decisions on the ADA.⁴¹

The first Supreme Court ADA case to address the definition of disability was *Bragdon v. Abbott*, a 1998 case involving a dentist who refused to treat an HIV infected individual outside of a hospital.⁴² In *Bragdon*, the Court found that the plaintiff's asymptomatic HIV infection was a physical impairment impacting on the major life activity of reproduction thus rendering HIV infection a disability under the ADA. In two 1999 cases the Court examined the definitional issue whether the effects of medication or assistive devices should be taken into consideration in determining whether or not an individual has a disability. The Court in the landmark

³⁸ 146 Cong. Rec. S6050 (daily ed. June 29, 2000)(remarks of Sen. Kennedy).

³⁹ "Update on Terri Sargent's Genetic Discrimination Case," [http://www.alpha1.org/programs/newsmakers_sargent.htm]

⁴⁰ [<http://www.eeoc.gov/press/4-18-01.html>].

⁴¹ For a discussion of the Supreme Court's ADA decisions see CRS Report RL31401, *The Americans with Disabilities Act: Supreme Court Decisions*.

⁴² 524 U.S. 624 (1998). For a more detailed discussion of this decision see CRS Report 98-599, *The Americans with Disabilities Act: HIV Infection is Covered Under the Act*.

decisions of *Sutton v. United Airlines*⁴³ and *Murphy v. United Parcel Service, Inc.*,⁴⁴ held, contrary to the interpretation given by the EEOC, that the “determination of whether an individual is disabled should be made with reference to measures that mitigate the individual’s impairment....”⁴⁵ In reaching this holding, the Court looked to the first prong of the definition of disability (having a physical or mental impairment that substantially limits one or more of the major life activities of an individual) and emphasized that the phrase “substantially limits” appears in the present indicative verb form “requiring that a person be presently — not potentially or hypothetically — substantially limited in order to demonstrate a disability.” In *Albertsons Inc. v. Kirkingburg*⁴⁶ the Court held unanimously that the ADA requires proof that the limitation on a major life activity by the impairment is substantial. The Court in *Sutton* also looked at the findings enacted as part of the ADA which stated that “some 43,000,000 Americans have one or more physical or mental disabilities” and found that this figure was inconsistent with the argument that the statute covered individuals without looking at the mitigating effects of medications or devices. The individualized nature of the inquiry into whether an individual was an individual with a disability was emphasized.

Although the Court’s decision in *Sutton* did not turn on the third prong of the definition of disability (being “regarded as having such an impairment”) the Court did address the interpretation of this part of the definition. There are two ways, the Court stated, that an individual can fall within the “regarded as” prong: (1) a covered entity mistakenly believes that a person has a physical impairment that substantially limits one or more major life activities, or (2) a covered entity mistakenly believes that an actual impairment substantially limits one or more major life activities. The Court found that, on its own, the allegation that an entity has a vision requirement in place does not establish a claim that the entity regards an individual as substantially impaired in the major life activity of working. The term “substantially limits” was regarded as significant. It requires “at a minimum, that plaintiffs allege they are unable to work in a broad class of jobs.” The Court emphasized that it was “assuming without deciding” that working is a major life activity and that the EEOC regulations interpreting “substantially limits” are reasonable and found that even using the EEOC interpretation, the plaintiffs in *Sutton* failed to allege adequately that their vision is regarded as an impairment that substantially limits them in a major life activity. Being precluded from being a global airline pilot was not sufficient since they could obtain other, although less lucrative jobs, as regional pilots or pilot instructors.

The “regarded as” prong was directly at issue in *Murphy*. In *Murphy* the Court held that the fact that an individual with high blood pressure was unable to meet the

⁴³ 527 U.S. 471 (1999).

⁴⁴ 527 U.S. 516 (1999).

⁴⁵ *Sutton v. United Airlines*. See also *Murphy v. United Parcel Service*, where the Court held that the determination of whether the petitioner’s high blood pressure substantially limits one or more major life activities must be made considering the mitigating measures he employs.

⁴⁶ 527 U.S. 555 (1999).

Department of Transportation (DOT) safety standards was not sufficient to create an issue of fact regarding whether an individual is regarded as unable to utilize a class of jobs. Like *Sutton*, the holding in *Murphy* emphasized the numerous other jobs available to the plaintiff.

The Supreme Court's decisions on the ADA did not directly address genetic discrimination and it is possible that the ADA could be interpreted to cover a particular genetic defect. However, 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. There are several factors that lead to this conclusion.

First, the Supreme Court in *Sutton* specifically struck down an interpretation by the EEOC regarding the use of mitigating factors and raised questions concerning the validity of the EEOC's interpretation. The Court also found no statutory authority for agency interpretation of the definition of disability. The EEOC had taken the position that whether or not an individual has a disability should be determined by what his or her condition would be without medication or an assistive device. Rejecting this EEOC interpretation, in *Sutton* the Supreme Court noted that no agency was given the authority to interpret the term "disability" but that because both parties accepted the regulations as valid "we have no occasion to consider what deference they are due, if any." Similarly, in *Murphy* the Court clearly stated that its use of the EEOC regulations did not indicate that the regulations were valid. However, in its earlier decision in *Bragdon v. Abbott*, the Court had found its conclusion that HIV infection was covered by the ADA to be "reinforced by administrative guidance issued by the Justice Department...." The cases subsequent to *Bragdon* did not examine this seeming contradiction so exactly how a future decision would view EEOC regulations and guidance is uncertain. This issue is especially important regarding potential cases of genetic discrimination since the EEOC has published guidance indicating that the ADA covers genetic discrimination,⁴⁷ and there are no reported cases.

Similarly, the Supreme Court showed little indication to examine the legislative history of the ADA. The Court in *Sutton* held that it was not necessary to consider the legislative history of the ADA regarding the issue of whether individuals should be examined in their uncorrected state or with the use of mitigating medications or devices. It found that the statutory language was sufficient to support its holding on this issue. Although the issue regarding genetic discrimination is distinct from that of the use of mitigating medications and devices, the Court's general reluctance to examine legislative history in *Sutton* may indicate that the language on genetic discrimination quoted above from the congressional debates also would not be examined.

The Court's reliance in *Sutton* upon the findings in the ADA that 43,000,000 Americans have one or more physical disabilities also indicates that the Court may not find genetic defects to be covered. The number of individuals cited in the findings as having a disability was seen by the Court as inconsistent with the

⁴⁷ EEOC Compliance Manual, Vol. 2, section 902, order 915.002,902-45 (1995).

argument that the statute covered individuals whose disabilities were mitigated by medications or devices. Since the prevalence of genetic defects is believed to be widespread, coverage of genetic defects could arguably include almost every individual. Thus, it is possible that the Court could use the same rationale as in *Sutton* to find genetic defects not included.

In *Bragdon v. Abbott*, where the Court found that HIV infection was covered under the ADA, the majority opinion spent considerable time discussing the immediate physiological effects of the infection. This would appear to be consistent with the holding in *Sutton* that the “substantially limits” definitional language requires that the substantial limitation not be potential or hypothetical. This reasoning could be contrasted to the situation presented by genetic defects which in many cases do not ever manifest. Interestingly, in his dissenting opinion in *Bragdon v. Abbott*, Chief Justice Rehnquist, who was in the majority in *Sutton*, stated that the argument regarding coverage of HIV infection “taken to its logical extreme, would render every individual with a genetic marker for some debilitating disease ‘disabled’ here and now because of some possible future effects.” Whether the Court would now share the Chief Justice’s view that such coverage of genetic discrimination is an invalid interpretation of the definition is uncertain, especially since the Court in *Bragdon* was discussing the first prong of the definition, not the “regarded as” prong which is the most likely basis for coverage of genetic defects.

In its recent cases the Court provided considerable guidance concerning the “regarded as” prong of the definition of disability, the most likely aspect of the definition to be used to find coverage of genetic defects. Including the requirement that the individual be regarded as “substantially limited” in a major life activity, the Court found that this language meant that being precluded from a particular job was not sufficient to be substantially limited in the major life activity of working if other jobs in the same class could be obtained. And when this specific issue was raised in *Murphy*, the plaintiff was not found to be regarded as substantially limited in the major life activity of working. The main point of this rather complicated discussion is that making the case that one is regarded as substantially limited in a major life activity, particularly the major life activity of working, is likely to be difficult.

The Supreme Court’s recent decisions do not directly address ADA coverage of genetic discrimination. They emphasize an individualized approach to the determination of whether an individual has a disability under the ADA. Although an argument could be made that the ADA would cover individuals with genetic defects in certain cases, the Court’s most recent decisions, particularly *Sutton* and *Murphy*, use reasoning that would make it unlikely that most ADA claims based on genetic discrimination would be successful.⁴⁸

⁴⁸ In testimony before the Senate Committee on Health, Education, Labor and Pensions, Andrew J. Imparato, the President and CEO of the American Association of People with Disabilities testified that “the ADA as drafted does provide some protections against genetic discrimination in employment, but the law has been interpreted by the Supreme Court and lower federal courts in a manner which weakens its protections. Whereas the ADA can be and has been used to stop genetic discrimination in some instances, the protections it affords offer little security to people with genetic markers and health conditions that have not yet
(continued...)

In addition, even assuming the ADA was found to apply, it may not protect employees from having their employers have access to their genetic information. Although the ADA prohibits an employer from making medical inquiries prior to a job offer, the employer may obtain medical information in certain cases after the offer of employment has been made. Assuming that the prohibitions against discrimination in the ADA would apply, it is difficult to prove that genetic information was the reason for discrimination. This raises issues relating to the privacy of genetic information.

Privacy

Although the Constitution does not expressly provide for a right to privacy, the Supreme Court has found some right to informational privacy.⁴⁹ However, these rights are limited by judicial deference to government's need to acquire the information and by the fact that such a constitutional right would be limited to state action. As a practical matter, this would mean that federal or state collections of information may receive some constitutional protection but the collection and use of information by private health plans or organizations would not be covered.⁵⁰ Certain federal statutes may provide some privacy protection for medical records. The Privacy Act of 1974, 5 U.S.C. § 552a, prohibits the disclosure of records maintained on individuals by federal government agencies except under certain conditions. Subsection 552a(f)(3) allows agencies to establish special procedures for individuals who wish to access their medical records. The intent of this provision as described in the House report was to ensure rules so that an individual who would be adversely affected by the receipt of such data may be apprized of it in a manner which would not cause such adverse effects.⁵¹

The Freedom of Information Act (FOIA), 5 U.S.C. §§ 552 *et seq.*, establishes a right of access to records maintained by agencies within the executive branch of the federal government. It contains several exemptions, including one for "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."⁵² Both the Privacy Act and FOIA may,

⁴⁸ (...continued)

developed into full-blown debilitating conditions." Testimony of Andrew J. Imparato, "Protecting Against Genetic Discrimination: The Limits of Existing Laws," Before the Senate Committee on Health, Education, Labor and Pensions, 107th Cong., 2d Sess. (Feb. 13, 2002), reprinted at <http://labor.senate.gov/Hearings-2002/feb2002/021302wit/021302wit.htm>

⁴⁹ See e.g., *Whalen v. Roe*, 429 U.S. 589 (1977).

⁵⁰ For a more detailed discussion of this issue see Gostin, "Genetic Privacy," 23 *J. of Law, Medicine & Ethics* 320 (1995).

⁵¹ H.Rept. 93-1416. 93d Cong., 2d Sess. 16-17 (1974).

⁵² 5 U.S.C. §552(b)(6).

then, provide some privacy protections for genetic information but they are limited in their scope and would not encompass information held by a private entity.⁵³

The ADA provides for some privacy protections for individuals with disabilities in the context of employment. Before an offer of employment is made, an employer may not ask a disability related question or require a medical examination.⁵⁴ The EEOC in its guidance on this issue stated that the rationale for this exclusion was to isolate an employer's consideration of an applicant's non-medical qualifications from any consideration of the applicant's medical condition.⁵⁵ Once an offer is made, disability related questions and medical examinations are permitted as long as all individuals who have been offered a job in that category are asked the same questions and given the same examinations.⁵⁶ The ADA also requires that information obtained regarding medical information be kept in a separate medical file.⁵⁷ The precise reach of the protections, especially regarding predictive genetic information is uncertain. As was discussed previously it is not clear whether the definition of disability under the ADA would cover an individual with a genetic predisposition to a condition when that condition has not manifested.⁵⁸

The Health Insurance Portability and Accountability Act (HIPAA) contains requirements for the standardization of electronically transmitted health insurance financial claims and administrative transactions, such as the submission of claims, processing of enrollments, verification of insurance eligibility, and payment and remittance advice. HIPAA required the Secretary of Health and Human Services (HHS) to make recommendations to Congress by August 1997 concerning the protection of privacy of individually identifiable health information and Congress had until August 1999 to enact legislation on this issue. If Congress did not enact legislation, HIPAA requires the Secretary of HHS to promulgate regulations on privacy protections. The Secretary of HHS issued final regulations on December 20, 2000.⁵⁹

⁵³ For a discussion of recent developments in medical records privacy see CRS Report RS20500, *Medical Records Privacy: Questions and Answers on the HIPAA Final Rule*.

⁵⁴ 42 U.S.C. §12112.

⁵⁵ EEOC, "ADA Enforcement Guidance: Preemployment Disability-Related Questions and Medical Examinations," Oct. 10, 1995.

⁵⁶ *Id.*

⁵⁷ 42 U.S.C. §12112(d)(3) and (4).

⁵⁸ One commentator has observed that "the complexity of the ADA, its differential treatment of prospective and existing employees, the especially wide latitude that employers have to require medical examinations and make medical inquiries at the post-offer stage and the centrality of the concept of 'disability' to the operation of the statute have led to confusion in the courts, and in many workplaces, about the precise contours of the ADA's privacy protections." Joanne L. Husted and Janlori Goldman, "The Genetics Revolution: Conflicts, Challenges, and Conundra: Genetics and Privacy," 28 *Am. J. L. and Med.* 285, 294 (2002).

⁵⁹ 65 Fed. Reg. 82461 (Dec. 20, 2000). For a more detailed discussion see CRS Report RS20500, *Medical Records Privacy: Questions and Answers on the HIPAA Final Rule*, and (continued...)

The final privacy regulations, which became effective on April 14, 2001, and were modified on August 14, 2002,⁶⁰ apply to health insurers, providers, and health care clearinghouses and give patients the right to inspect, copy and in certain situations, amend their medical records. The regulations cover all personal health information in paper, oral or electronic form. Individually identifiable health information is defined broadly and includes genetic information as well as information about an individual's family history.⁶¹ Covered entities are required to have in place reasonable safeguards to protect the privacy of patient information and limit the information used or disclosed to the minimum amount necessary to accomplish the intended purpose of the disclosure. Civil money penalties are provided, although there is no private right of action, and egregious violations carry federal criminal penalties of up to \$250,000 and ten years in prison. Although these regulations are general and not specific to genetics, they will have an effect on genetic information. In the comments to the regulations, the Department noted that many commentators requested additional protections for sensitive information, including genetic information. In response, the Department noted that generally the regulations do not differentiate among types of protected health information.⁶²

State Statutes

Although there is limited federal law relating to the use of genetic information, many states have enacted statutes dealing with various aspects of these issues. Early state statutes focused on particular genetic conditions. The first statute to prohibit discrimination based on a genetic trait was enacted in North Carolina and prohibited employment discrimination based on the sickle cell trait. In 1991 Wisconsin became the first state to enact a comprehensive law to prohibit discrimination based on genetic test results. Currently, the states vary in their provisions with some prohibiting discrimination in employment while others deal solely with discrimination in insurance. A recent survey of state law found that thirty-one states have enacted genetic nondiscrimination in employment laws.⁶³ A related survey found that thirty-four states have passed laws strictly prohibiting the use of genetic

⁵⁹ (...continued)

CRS Report RS20934, *A Brief Summary of the Medical Privacy Rule*.

⁶⁰ 67 Fed. Reg. 53181 (Aug. 14, 2002).

⁶¹ There are additional protections regarding "psychotherapy notes."

⁶² 65 Fed. Reg. 82731 (Dec. 20, 2000). A hearing in the 107th Congress examined the issues relating to the privacy of genetic information. See "Privacy Concerns Raised by the Collection and Use of Genetic Information by Employers and Insurers" Before the House Subcommittee on the Constitution of the House Judiciary Committee, 107th Cong., 2d Sess. (September 12, 2002).

⁶³ National Conference of State Legislatures Genetics Tables, State Genetics Employment Laws, [<http://www.ncsl.org/programs/health/genetics/ndiscrim.htm>]. See also, "Genetic Information and the Workplace: Enacted Legislation," [http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/workplace.htm].

information for risk selection and risk classification purposes.⁶⁴ One of the most contentious aspects of the state legislation has been the definition of genetic information. Some states, like Michigan, limit nondiscrimination protections to the results of genetic tests. On the other hand, New Jersey prohibits the use of information about genes, gene products or inherited characteristics that may derive from an individual or family member. This would include information such as family history which is often used in insurance underwriting.

Although these state statutes do provide some types of coverage, they do not cover employer self-funded plans providing private health insurance for employees and their dependents. These plans are exempt from state insurance laws due to the preemption provision in the federal Employee Retirement Income Security Act (ERISA).⁶⁵ Since it has been estimated that over one-third of the nonelderly insured population obtains its coverage through self-funded plans and these types of plans are increasing, the ERISA exemption limits the application of state laws significantly.⁶⁶

Legislation in the 106th Congress

Although legislation specifically relating to genetic discrimination and privacy was not enacted during the 106th Congress, a provision relating to health insurance was considered in the conference on H.R. 2990. The Senate amended H.R. 2990 as passed by the House, striking all the language after the enacting clause and substituting the language in S. 1344. This Senate bill would have amended ERISA, the Public Health Service Act and the Internal Revenue Code to prohibit health plans or health insurance issuers, in both group and individual markets, from using predictive genetic information to set premiums. It also contained confidentiality provisions.⁶⁷

Senator Daschle had offered a more comprehensive amendment to the FY2001 Labor-HHS Appropriations bill, S. 2553. It would have prohibited insurance companies from raising premiums or denying coverage on the basis of genetic tests and would have also barred employers from using predictive genetic information to make employment-related decisions. The amendment was defeated by a vote of 54-44.

⁶⁴ National Conference of State Legislatures Genetics Tables, State Genetic Nondiscrimination in Health Insurance, [<http://www.ncsl.org/programs/health/genetics/ndishlth.htm>].

⁶⁵ 29 U.S.C. §§ 1001-1145.

⁶⁶ Hudson, "Genetic Discrimination and Health Insurance: an Urgent Need for Reform," 270 Science 391 (1995); Rothenberg, "Genetic Information and Health Insurance: State Legislative Approaches," 23 J. of Law, Med. & Ethics 312 (1995).

⁶⁷ For a more detailed discussion see CRS Report RL30144, *Side-by-Side Comparison of H.R. 2990 and the Senate Amendment for Patient Protection*.

Legislation in the 107th Congress

Legislation relating to genetic discrimination and privacy continued to be a major issue in the 107th Congress. The Senate version of the Patient Protection Act, S. 1052, which passed the Senate on June 29, 2001, contained an amendment prohibiting certain genetic discrimination by group health plans and health insurance issuers. It also contains a provision relating to confidentiality.⁶⁸ Congress did not pass the legislation prior to the adjournment of the 107th Congress.

Other Senate legislation in the 107th took various approaches. S. 318, introduced by Senator Daschle, would have prohibited genetic nondiscrimination in health insurance and employment. S. 1995 sponsored by Senators Snowe, Frist and Jeffords, also would have prohibited genetic discrimination in insurance and employment but was less broad than S. 318.⁶⁹ S. 19, the Protecting Civil Rights for all Americans Act introduced by Senator Daschle, contained nondiscrimination provisions relating to insurance and employment. Senator Snowe also introduced S. 382, the Genetic Information Nondiscrimination in Health Insurance Act of 2001, which would have prohibited discrimination in insurance. S. 450, the Financial Institution Privacy Protection Act of 2001 introduced by Senator Nelson, contained provisions protecting the privacy of health information, including genetic information.⁷⁰

In the House, Representative Slaughter introduced H.R. 602, the Genetic Nondiscrimination in Health Insurance and Employment Act, which would have prohibited genetic discrimination in insurance and employment. H.R. 602 was paralleled by S. 318 in the Senate.

Legislation in the 108th Congress

Legislation relating to genetic discrimination and privacy continues to be a major issue in the 108th Congress. Several bills have been introduced to address genetic discrimination and privacy. For example, S. 16, the Equal Rights and Equal Dignity for Americans Act of 2003 introduced by Senator Daschle on January 17, 2003, contained nondiscrimination provisions relating to insurance and employment. On May 1, 2003, Representative Slaughter introduced H.R. 1910, The Genetic Nondiscrimination in Health Insurance and Employment Act, which prohibits genetic discrimination in insurance and employment. H.R. 1910 is a companion to S. 1053, introduced by Senator Snowe on May 13, 2003, in the Senate.

⁶⁸ For a more detailed discussion of the Patient Protection Legislation see CRS Issue Brief IB98017, *Patient Protection and Managed Care: Legislation in the 107th Congress*.

⁶⁹ For a comparison of S. 1995, 107th Cong., and H.R. 602/S. 318, 107th Cong., see CRS Report RL31527, *Genetic Non-Discrimination in Insurance and Employment: Side-by-Side Analysis of Leading House and Senate Bills*.

⁷⁰ For a more detailed discussion of this legislation see CRS Report RS20185, *Privacy Protection for Customer Financial Information*.

On May 21, 2003, the Senate Health, Education, Labor, and Pensions (HELP) Committee unanimously passed a manager's substitute amendment to S. 1053 designed to protect the privacy of genetic information as well as to protect individuals from discrimination in health insurance and employment, based on their genetic information.⁷¹ The bill prohibits health insurance plans from denying enrollment or charging higher premiums to individuals based on the individual's or family member's genetic information. In addition, the bill bans the collection, use and disclosure of genetic information for insurance underwriting purposes. In the employment context, this bill prohibits the use of genetic information in employment decisions, such as hiring, firing, job assignments and promotions. The bill also prevents the acquisition and disclosure of genetic information as well as applies the procedures and remedies authorized under the Civil Rights Act of 1964 to cases of genetic discrimination.

⁷¹ Press Release, HELP Committee, HELP Cmte. Passes Bipartisan Genetic Anti-Discrimination Legislation (May 21, 2003).