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REVIEW

# Genetic Privacy: From the Laboratory to the Legislature

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Over the past few years, I have often been approached by researchers who tell me that they wonder if they are doing the right thing by looking for this or that disease gene. They are often motivated in their work by the important goal of ultimately being able to cure devastating diseases. Yet, at the same time, they realize that there is generally a lengthy gap between the availability of genetic testing and the development of a treatment. They worry about what happens when testing starts on the patients and they become uninsurable or unemployable as a result of genetic knowledge.

The concern of researchers is shared by members of the public. An April 1995 Harris Poll found that 86% of people are concerned about the prospect of employers and insurers using genetic tests before deciding whether to hire or insure someone. Such possibilities led Congressman Obey, at the National Institutes of Health (NIH) Reauthorization hearings, to ask Francis Collins, director of the Human Genome Project, whether there should be a ban on NIH grants to researchers in states that do not have laws protecting genetic privacy.

The purpose of this article is to explore the reasons why genetic information is particularly sensitive and to develop a policy framework for protecting genetic privacy. The need for protection of genetic information is due, in part, to its unique nature and history. George Annas describes its importance by saying that "The highly personal nature of the information contained in DNA can be illustrated by thinking of DNA as containing an individual's 'future diary.' A diary is perhaps the most personal and private document a person can create. It contains a person's innermost thoughts and perceptions and is usually hidden and locked to assure its secrecy. Diaries describe the past. The information in one's genetic code can be thought of as a coded probabilistic future diary because it describes an important part of a unique and personal future" (Annas and Elias 1992, p. 9).

The highly personal nature of genetic information and the potentially volatile effects of its disclosure have been documented in a variety of studies. Learning genetic information about themselves can cause people to view themselves differently. Carriers of genes for recessive disorders who are healthy may consider themselves unmarriageable based on their own genetic information, or others may treat them differently based on their genetic status. In a follow-up study 8 years after Tay–Sachs carrier screening, 19% of the individuals remained concerned about the results (Zeesman et al. 1984). Some people who have tested positive for Huntington's disease have needed to be hospitalized for depression (Andrews et al. 1994, p. 88). Even individuals who test negative may be profoundly affected. Some may experience survivor's guilt when siblings and other relatives have a genetic mutation, such as the gene for Huntington's disease, and they do not (Wexler 1991). The results of genetic testing can cause people to rethink their own identities. In one case, a man whose parent had Huntington's disease assumed that he would get the disease as well. He lived his life on the assumption that he would die young. He engaged in dangerous sports and did not save money for the future. When he was tested and learned he did not have the gene, he ended up embezzling from his company (Huggins et al. 1992).

When genetic information is released to others, there are further risks. Schools, mortgage companies, insurers and other institutions may wish to make decisions about people based on their genotypes. In one instance, a medical school did not want to admit an applicant at risk for Huntington's disease on the grounds that it was not worth training someone who would have a shortened practice life (National Commis-

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sion 1977, p.85). An insurance company refused to offer coverage for breast cancer to the daughter of a woman with the *BRCA1* gene (M.J. Kahn unpubl.).

Courts may make increasing use of genetic testing as well. A divorcing parent could convince a court to order genetic testing on the other asymptomatic parent with a claim that it is better for a child to be with a parent who will live longer. Dorothy Nelkin points out that physicians are increasingly being put into the role of "double agents"—with dual loyalties to the patient and to the patient's school, employer, potential insurer, relative, or child (Nelkin and Tancredi 1989, p. 164).

Genetic information is also particularly sensitive because its use has had a sordid past. It has been used as a basis for genocide in some countries and, in this country, was used as a basis for involuntary sterilization of tens of thousands of people thought to be unfit. The stigmatization of people with genetic conditions can be seen even today. California anchorwoman Bree Walker is affected with ectrodactyly, a mild genetic condition, which fused the bones in her hand. When she decided to continue her pregnancy of a fetus with the same condition, a radio talk show host and her audience attacked the decision as irresponsible and immoral.

Even the way that genetic research results are reported in the medical literature may cause stigmatization. For example, some of the articles that describe the discovery of particular genes include information about the annual cost of caring for a person with those disorders, unintentionally giving a subtle message that such a person drains society's resources and perhaps never should have been born.

There is a rich body of literature suggesting the importance of control of private information about oneself. The control of information is seen as important to people's psychological well-being, as a way to create their self-identity and a way to enter into intimate relationships with other people by parsing out information as the relationship progresses. Control of information is seen as enhancing people's autonomy. According to Charles Fried "[T]o respect, love, trust, feel affection for others and to regard ourselves as the objects of love, trust, and affection is at the heart of our notion of ourselves as persons and privacy is the necessary atmosphere for these attitudes and actions. . . ." (Fried 1968, pp. 477–478).

In the clinical setting, privacy is thought to have additional practical benefits. The policy goal behind protecting the confidentiality of health care information is to encourage people to go to their physician or psychologist or psychiatrist and provide the detailed personal information that might be necessary for treatment, even when that information might be embarrassing or potentially stigmatizing.

The sensitive nature of genetic information has been recognized throughout the world; however, the level and kind of protection it receives varies from country to country, because of differences in how health care is financed and delivered. Despite the importance of genetic privacy, it is not well protected under American law. Existing medical confidentiality protection is not sufficient for genetic information. In some situations, it does not even apply. For example, medical information collected in the workplace rather than the doctor's office is not protected in some states, so genetic screening and monitoring of employees is not covered (Andrews and Jaeger 1991). Even genetic information collected in a traditional health care setting may be unprotected depending on *who* collects it. Some existing medical confidentiality statutes only protect medical information in the hands of *doctors* and will not cover genetic information in the hands of Ph.D. geneticists or genetic counselors (Andrews 1987, p. 191).

Moreover, even in states where genetic information is protected and cannot be released without the individual's permission, this is not sufficient protection for the types of harm we are actually concerned about. As long as insurers and employers can continue to ask people to "consent" to the release of their genetic information, people will be discriminated against based on their genotype, no matter what the state's law is on medical confidentiality.

## A GENERAL POLICY FRAMEWORK

What type of policy framework would respond to the concerns about privacy and unfair uses of genetic information? A three-prong approach seems appropriate (see Table 1). The first is to assure that people have control over the genetic information that is generated about them. The second is to give them control of who has access to that information. The third is to prevent discrimination against people based on genetic information. A few state legislatures have begun to adopt one or more of these types of protection,

**Table 1. Policies for handling genetic information**

*Voluntariness*

Genetic testing of an individual may not be undertaken without advance informed voluntary consent by that individual or, if the individual is a minor or incompetent, that individual's guardian or legal representative, except for law enforcement purposes in situations in which probable cause has been established and to establish paternity under the terms of the paternity act.

*Confidentiality*

The results of genetic testing shall be confidential and shall be released only with the advance informed voluntary written consent of the individual or, if the individual is a minor or incompetent, that individual's guardian or legal representative. Insurers and employers may not ask for or require collection of genetic information about an individual.

*Protection Against Discrimination*

No person, firm, corporation, unincorporated association, state agency, unit of local government or public or private entity shall deny or refuse employment; deny, refuse or limit employment benefits; or discharge from employment any person on the basis of a person's genetic characteristics that may be associated with a disability or illness in that person, that person's future offspring, or that person's relatives.

No public or private health insurer, health maintenance organization, health plan, or insurance agent dealing in health insurance shall deny coverage, refuse to enroll, require a higher premium, charge on a differential basis, exclude coverage of a particular condition or service, or cancel coverage of any person on the basis of a person's medical risks, including genetic risks, which may be associated with a disability or illness in that person, that person's future offspring, or that person's relatives.

but in general the coverage of the laws has been extremely narrow.

The first protection necessary is an assurance that genetic testing is voluntary and informed. This means that scientists should not undertake a genetic test on a tissue sample that is linked to an identifiable patient unless the patient has been asked for permission to undertake that type of test. It is not a sufficient ethical constraint for researchers to perform such testing and then disclose to the individual any abnormal test result. People may want to keep genetic information private, even from themselves. Less than 15% of at-risk individuals choose to obtain Huntington's disease testing (Bloch et al. 1989). Similarly, only 4%–24% of the general population of reproductive age chooses to have cystic fibrosis (CF) carrier screening, even when it is offered without charge (Tambor et al. 1994).

Similarly, health care professionals should not undertake genetic testing on individuals without their consent, as has sometimes been done in the case of pregnant women (Rowley et al. 1989). The data on the psychological and social impact of genetic information, as well as its historical misuse, indicates that genetic testing should not be treated like a simple blood test.

The policy that genetic testing be voluntary is supported by the recommendations of various committees and commissions that have addressed the issue (Committee for the Study of Inborn Errors of Metabolism 1975; Andrews et al. 1994). In its statement, the NIH Workshop on Reproductive Genetic Services stressed the point by saying that "Reproductive genetic services should be meticulously voluntary" (Thomson and Rothenberg 1994). A similar emphasis on voluntariness is found in the *Handbook for Institutional Review Boards* prepared by the NIH Office for Protection from Research Risks. Legislation in New Hampshire makes this point by stating that except with respect to paternity testing, newborn screening, and forensic testing, "[no genetic testing shall be done . . . without the prior written and informed consent of the individual to be tested" [N.H. Rev. Stat. Sec. 141:H:2 (Art. II) (1995)].

For people who agree to undergo genetic testing, the confidentiality of their information must be protected. This can be done by measures that expand upon state medical confidentiality laws. A statute in Colorado provides such protection saying, "Genetic information is the unique property of the individual to whom the information

pertains. . . . Information derived from genetic testing shall be confidential and privileged. Any release, for purposes other than diagnosis, treatment, or therapy, of genetic testing information that identifies the person tested with the test results released requires specific written consent by the person tested" [(Colo. Stat. Ann. Sec. 10-3-1104.7(3)(a) (West Publishing Co. 1994)].

Moreover, individuals and entities generating or collecting genetic information should explain their confidentiality protection to people seeking services in advance of delivering those services. Along those lines, for example, the Institute of Medicine Report, *Assessing Genetic Risks*, states that "If there are any circumstances in which the geneticist or other health care professional could breach confidentiality and disclose information to a spouse, relative, or other third party, for example, to an employer, those circumstances should be explained in advance of testing; and, if the patient wishes, the patient should be given the opportunity to be referred to a health care provider who will protect confidentiality" (Andrews et al. 1994). Similarly, the recommendations from an American Association for the Advancement of Science–American Bar Association Conference were that "Researchers engaged in pedigree studies incorporate into their research protocols provisions on what information will be collected and from whom; what information will be recorded and in what form; who will have access to information and under what circumstances; and plans for the retention and disposition of pedigree data once the research ends"(Frankel and Teich 1992).

The third concern is that in situations in which third parties gain genetic information about an individual that information should not be used against the individual (Billings et al. 1992). The prohibition of genetic discrimination in employment took an important turn in March 1994, when the Equal Employment Opportunities Commission (EEOC) provided guidance about how the Americans with Disabilities Act (ADA) would apply to an individual who is presymptomatic for a genetic disease. The ADA prohibits employers with more than 15 employees from refusing to hire or otherwise discriminating against people with disabilities or who are regarded as having disabilities. In its compliance manual, the EEOC wrote that it is illegal for an employer to discriminate against a person based on genetic information relating to illness, disease, or other disorders. As an example, the EEOC indicated that an employer cannot refuse to hire an individual just because the person's genetic profile reveals an increased susceptibility to colon cancer.

This interpretation may not go far enough, however, as it does not specifically address whether someone can be denied a job because he or she is a carrier of a recessive disorder such as CF and the potential employer does not want to pay the health care costs of potential future affected children. Nor does it address the privacy concerns per se, as employers are apparently still permitted under the ADA to order genetic testing on individuals who have been offered employment, even without the individual's permission, as long as they do not use that information in unfair ways.

A few state legislatures have also attempted to protect against genetic discrimination in employment and insurance. For various reasons, these laws are also too narrow. In Minnesota, the protection extends only to people who are presymptomatic for genetic diseases, not people who are carriers of recessive disorders [Minn. Stat. Sec. 72A.139 (1995)]. In Wisconsin, the protection extends only to those people who are discriminated against by insurers based on a DNA test, not those who are discriminated against based on family history or a test of gene proteins [Wisc. Stat. Ann. Sec. 631.89 (West Publishing Co. 1995)]. In North Carolina, the law only protects people possessing sickle cell trait or hemoglobin C trait [N.C. Gen. Stat. Sec. 58-65-70 (1994)].

The widespread use of genetic tests creates the possibility of a genetic underclass, where asymptomatic people are discriminated against based on information about their relatives, their future health status, or the health status of their future children. Table 1 gives examples of the three levels of protection that would be necessary to ensure that the application of knowledge from the Human Genome Project does not do more harm than good.

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## REFERENCES

Andrews, L. 1987. *Medical genetics: A legal frontier.* American Bar Foundation, Chicago, Ill.

Andrews, L. and A. Jaeger. 1991. Confidentiality of genetic information in the workplace. *Am. J. Law Med.* **17:** 75–108.

Andrews, L., J.E. Fullarton, N.A. Holtzman, and A.G. Motulsky. 1994. *Assessing genetic risks: Implications for health and social policy*. National Academy of Sciences Press, Washington, D.C.

Annas, G.J. and S. Elias, eds. 1992. *Gene mapping: Using law and ethics as guides*. Oxford University Press, New York.

Billings, P.R., M.A. Kohn, M. de Cuevas, J. Beckwith, J.S. Alper, and M.R. Natowicz. 1992. Discrimination as a consequence of genetic testing. *Am. J. Hum. Gen.* **50:** 476–482.

Bloch, M., M. Fahy, S. Fox, and M.R. Hayden. 1989. Predictive testing for Huntington's Disease: II. Demographic characteristics, life-style patterns, attitudes, and psychological assessments of the first fifty-one test candidates. *Am. J. Med. Gen.* **32:** 217–224.

Committee for the Study of Inborn Errors of Metabolism, Division of Medical Sciences, Assembly of Life Sciences, National Research Council, 1975. Recommendations in *Genetic Screening: Programs, Principles, and Research*.

Frankel, M.S. and A.H. Teich. 1992. *Ethical and legal issues in pedigree research*. American Association for the Advancement of Science, Washington D.C.

Fried, C. 1968. Privacy. *Yale Law J.* **77:** 475–493.

Huggins, M., M. Bloch, S. Wiggins, S. Adam, O. Suchowersky, M. Trew, M. Klimek, C.R. Greenberg, M. Elef, L.P. Thompson, J. Knight, P. Macleod, K. Girard, J. Theilman, A. Hendrick, and M.R. Hayden. 1992. Predictive testing for Huntington's Disease in Canada: Adverse effects and unexpected results in those receiving a decreased risk. *Am. J. Med. Gen.* **42:** 508–515.

National Commission for Control of Huntington's Disease and its Consequences. 1977. Report Volume I: Overview. Department of Health, Education and Welfare publ. no. (NIH) 78-1501.

Nelkin, D. and L. Tancredi. 1989. *Dangerous diagnostics: The social power of biological information*. Basic Books, New York.

Rowley, P.T., S. Loader, C.J. Sutera, and M. Walden, 1989. Do pregnant women benefit from hemoglobinopathy carrier detection? *Ann. N.Y. Acad. Sci.* **565:** 152–160.

Tambor, E.T., B.A. Bernhardt, G.A. Chase, R.R. Faden, G. Geller, K.J. Hofman, and N.A. Holtzman. 1994. Offering cystic fibrosis screening in an HMO population: Factors associated with utilization. *Am. J. Hum. Gen.* **55:** 626–637.

Thomson, E.J. and K. Rothenberg. 1994. *Women and prenatal testing: Facing the challenges of genetic technology*. Ohio State University Press, Columbus, OH.

Wexler, N.S. 1991. Presymptomatic testing for Huntington's disease: Harbinger for the new genetics. In Proceedings of the Twenty-fifth Council for International Organization of Medical Sciences Conference, Japan 1991 (ed. Z. Bankowski and A.M. Capron).

Zeesman, S., C.L. Clow, L. Cartier, and C.H. Scriver. 1984. A private view of heterozygotes: Eight-year follow-up study on carriers of the Tay-Sachs gene detected by high school screening in Montreal. *Am. J. Med. Gen.* **18:** 769–778.