



# Controversies *in* Cancer Care

## Genetic Testing

### *Issues Related to Privacy, Employment, and Health Insurance*

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The discovery of the structure of DNA in 1953 opened the door to genetic research on an unparalleled scale, leading to the mapping of the human genome in 2000. As genes were discovered and their effects determined, it became clear that genes could be responsible in causing disease with certainty (eg, Huntington's chorea) or in bestowing protection against or propensity for the potential future development of disease. Medical researchers have been fascinated by the prospect that genetic engineering could allow the repair of defective disease-related genes or the alteration of genes to impart protection.

Controversial issues stem from the fact that, long before genetic science develops to the point of successful treatment of genetic disease, there will be an accumulation of knowledge that allows researchers to predict with reasonable accuracy the probability that a person will develop certain diseases. This discussion will be confined to posing the questions of how genetic knowledge and testing should be used by employers and the insurance industry, and the responsibility of government in protecting the individual's genetic information.

The authors also wish to draw the reader's attention to the testimony of Harold P. Coxson, Esq. before the Senate Committee on Health, Education, Labor and Pensions on July 20, 2000. This well-prepared testimony contains a wealth of information that will form a substantial basis for the following discussions.<sup>1</sup>

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### Current Federal and State Laws on Genetic Testing

#### *Federal*

The Americans with Disabilities Act (ADA) has specific provisions prohibiting absolutely any medical inquiries or examinations at the preoffer stage of the employment application process. Genetic testing or history would, therefore, be excluded. However, upon an offer of employment, the prospective employer may condition the offer based on the successful completion of a medical examination. The ADA does not limit the scope of examination, providing that all such applicants are treated the same, the information is confidentially collected and maintained, and the results are used without discrimination. That is, the offer would only be withdrawn where the individual could not perform the essential functions of the job even with reasonable accommodation. Because genetic testing usually addresses future health probabilities, it is unlikely that the ADA would allow this in a pre-employment situation.

The issue of presumed disability under the ADA is most unlikely with genetic disorders when the individual has a predisposition for developing a disease in the future, determined or undetermined.<sup>1</sup>

British insurers voluntarily have agreed to address the use of genetic testing for underwriting insurance policies. On October 27, 2001, they agreed with their government to a 5-year moratorium on using genetic information on all but the highest value policies (life insurance policies of £500,000, and other policies of £300,000).

#### *State*

Traditionally, states have been responsible for legislation governing the insurance industry. Table 1 provides a summary of 21 states that have prohibited employment discrimination and 19 that have enacted privacy laws related to genetic testing.<sup>1</sup>

### Employment Questions

Employers who administer self-insured health plans provide the majority of healthcare coverage in the United

**Table 1. US States that have Prohibited Employment Discrimination or Enacted Privacy Laws Related to Genetic Testing Information**

State	Year	Employment Laws	Privacy Laws
Arizona	1997	✓	✓
California	1998	✓	✓
Connecticut	1997	✓	
Delaware	1998	✓	✓
Illinois	1997	✓	✓
Iowa	1997	✓	
Kansas	1999	✓	
Maine	1998	✓	
Missouri	1998	✓	✓
Michigan	2000	✓	✓
Nevada	1999	✓	✓
New Hampshire	1995	✓	✓
New Jersey	1996	✓	✓
New York	1996	✓	✓
North Carolina	1997	✓	
Oklahoma	1998	✓	
Oregon	1995	✓	✓
Rhode Island	1992	✓	
Texas	1997	✓	✓
Vermont	1997	✓	✓
Wisconsin	1991	✓	
Colorado			✓
Florida			✓
Georgia			✓
New Mexico			✓
South Carolina			✓
Virginia			✓

States. Consequently, it is important to consider questions about the use of genetic information by employers. Two such controversial questions include the following: 1) should employers have the right to ask for or to use individual genetic information in decisions for hiring or promoting employees, or both?; and 2) is there a distinction between asking for genetic testing and requesting the disclosure of the results of a previously performed test or details of a person's history?

There is little doubt that the use of genetic information by employers, in the absence of illness as criteria for employment or promotion, will not be tolerated by the government. The states that have initiated legislation have made it clear that the request for genetic testing is unacceptable in these circumstances. However, the state legislation is much less clear in establishing the protection of information derived from genetic tests that have already been performed.<sup>1-4</sup>

### Insurance Questions

It is also important to consider controversial questions about genetic testing as related to insurance coverage.

Three such questions are the following: 1) should health insurers allow benefits for genetic testing in the absence of a diagnostic purpose or risk? 2) should health, life, disability, or long-term care insurers, or the combination of all four, use genetic information in underwriting to determine insurability or rates?; and 3) is there a difference between asking for testing and using previously performed test results or the details of a person's history?

Benefits for, and therefore coverage of, genetic testing is determined by the establishment of medical necessity. Medical necessity is typically defined in writing and can be found in the insured's contract. Perhaps the more difficult subset of this question is when does testing comprise preventive care (not an insured benefit under some contracts) as opposed to diagnostic care? The simple position is that screening, in the absence of risk factors including family history (eg, disease in at least two first-degree relatives), is considered to be preventive care, while testing in the presence of a significant family history and other risk factors constitutes diagnostic care because of the opportunity it offers to detect and affect the future outcome of silent disease. As an example, Blue Cross and Blue Shield of Texas has developed a medical policy with criteria to determine when genetic testing is diagnostic and, therefore, a covered benefit even in the absence of preventive care coverage (eg, testing for the presence of *BRCA1* and *BRCA2* genes for a genetic predisposition to breast cancer).

Some argue that if insurers could have access to genetic testing, they could more accurately determine an individual's risk of illness and could assign that risk to those responsible by adjusting insurance premiums accordingly. However, the pillar of insurance has been the sharing of risk over a large population, such that the risk borne is not just shared but is diluted such that it is acceptable and affordable to the individual. Would the more accurate assignment of risk to subpopulations result in a more or less equitable distribution of risk? The present actuarial assignment of risk is based on distribution over the greatest population possible. To do otherwise would compromise the very principles of insurance. It is primarily based on this premise that most insurers will not ask for genetic testing in their underwriting process. However, to ignore the results of genetic testing already performed would be contrary to the avoidance of adverse selection, which comes into play when individuals seek insurance coverage only after they become aware of an illness or unusual risk. The extent to which states have limited the use of genetic information is variable.

### Legislative Questions

Legislative questions in need of consideration include the following: 1) what is the responsibility of federal versus state legislative bodies in establishing protection for the individual?; 2) what is necessary to protect the privacy of genetic information?; 3) what is necessary to protect the use of genetic information in insurance underwriting and employment?; and 4) what is the definition of, and consequently what constitutes the legitimate ownership of, genetic material?

The rush of legislation both at the federal and state levels, coupled with the more ominous absence of protection in 60% of the nation's states, indicates the need for coordinated and equitable legislation throughout all the states. This can be achieved only at the federal level with full state representation. Such legislation must address confidentiality concerns and must define specifically when and how genetic information can be obtained and used.<sup>5-8</sup> Still not addressed is the question of the ownership of genetic material.

Throughout these discussions, a need has evolved for coordinated national legislation covering genetic testing and privacy. With the multiplicity of national corporations, and the interstate movement and transfer of their employees, insurers have long recognized the need for the equitable application and consistency of benefits, regardless of the location of the employee. The issue of genetic testing and how it will be used in underwriting or be allowed in benefit poses a unique challenge in both jurisprudence and medical practice. It appears that individual states may need to work with the federal government to provide uniform rules governing the use of genetic information.<sup>9-15</sup>

## References

1. Coxson, Harold P. Genetic information discrimination in the workplace: testimony before the senate committee on health, education labor and pensions, July 20, 2000. Available at: [www.senate.gov/~labor/hearings/july00hr/072000wt/0](http://www.senate.gov/~labor/hearings/july00hr/072000wt/0). Accessed November 5, 2001.
2. Five-year moratorium on gene tests, Great Britain. Available at: <http://money.telegraph.c>. Accessed October 27, 2001.
3. Equal Employment Opportunity Commission. Policy guidance on Executive Order 13145: to prohibit discrimination in federal employment based on genetic information. Available at: <http://www.eeoc.gov/docs/guidance-genetic.html>. Accessed October 2, 2001.
4. Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice. Genetic information and the workplace. Available at: [http://www.nhgri.nih.gov/HGP/Reports/genetics\\_workplace.html](http://www.nhgri.nih.gov/HGP/Reports/genetics_workplace.html). Accessed November 5, 2001.
5. Genetic Alliance. Genetic discrimination in Health Insurance and Employment Act: statement of the Genetic Alliance. Available at: <http://www.geneticalliance.org/geneticissues/gainsurance.html>. Accessed November 5, 2001.
6. National Center for Policy Analysis. Health care issues, insurance and genetic privacy. Available at: <http://www.ncpa.org/health/pdh/jan98.htm>. Accessed November 5, 2001.
7. Shore S. Genetic privacy. *Associated Press*. Available at: <http://www.netlink.de/gen/zeitung/1998/980617a.html>. Accessed November 5, 2001.
8. Cohen MM. Background statement: genetic testing and insurance. *Am J Hum Genet*. 1995;56:327-331.
9. Illinois Compiled Statutes Annotated. Ch. 215, Insurance Act 5. Illinois Insurance Code Article XX. Accident and health insurance: use of information derived from genetic testing 5/356 v. July 12, 2001.
10. Colorado Revised Statutes Annotated. Title 10. Insurance, regulation of insurance companies: Art. 3. Regulation of insurance companies; Part 11. Unfair competition—deceptive practices, 10-3-1104.7.
11. Code of Georgia. Title 33. Insurance, Ch. 54. Genetic testing, 33-54-1.
12. New York Civil Rights Law. Laws 1909. Ch. 14.
13. Texas Labor Code. Discriminatory use of medical information, Ch. 21, Subchapter H, Sect. 2, Sect. 21.401.
14. Edwards JG, Brooks KA, Aiken JH, et al. Developing genetic privacy legislation: the South Carolina experience. *Genet Test*. 1998;2:37-41.
15. Anderlik MR, Lisko EA. Medicolegal and ethical issues in genetic cancer syndromes. *Semin Surg Oncol*. 2000;18:339-346.