Am. J. Hum. Genet. 56:327-331, 1995

# BACKGROUND STATEMENT
# Genetic Testing and Insurance

The Ad Hoc Committee on Genetic Testing/Insurance Issues

## Background

The rapid expansion of genetic technology raises complex questions about the relationships among practitioners, patients, and insurers. In 1991, The American Society of Human Genetics (ASHG) appointed an Ad Hoc Committee on Insurance Issues in Genetic Testing to explore these issues. The purpose of this paper is to assist members of the ASHG and others who provide genetic services to better understand the issues so that they can consider the policy options that must be resolved. We hope this will prepare the ASHG membership to anticipate problems and to foster further discussion within the society, which will lead to an ASHG position paper on the issues.

Many other groups are considering these issues and developing background papers and policy recommendations (Office of Technology Assessment, U.S. Congress 1988; Mitchell et al. 1991; Moseley et al. 1991; Pokorski 1992; NIH-DOE 1993; Ostrer et al. 1993), and a number of scholars are turning their attention to this area (Andrews 1991; Holtzman and Rothstein 1992; Kass 1992; Murray 1992). For those interested in a brief background on the basic features of the American insurance system, we recommend the NIH-DOE (1993) report and the review by Ostrer et al. (1993).

## The Basic Premise of Insurance

Insurance products are developed to provide financial protection against unanticipated loss. While everyone will die and most will at some time become seriously ill, we generally do not expect to die early, and we all believe it will be someone else who will be disabled or become ill. Insurance is sold to replace income or to pay for health care on the chance that one of these unanticipated events occurs. It is a means of mitigating loss. Standard premiums are calculated on the expected outcome for large numbers of individuals with similar risks and are expected to spread the cost of the loss among a group. Prior to issuing a policy, however, insurers must determine the risk that an individual client presents and must adjust their premium to acknowledge that risk. The process is called *underwriting*.

The commercial insurance industry in the United States has traditionally served the important functions of providing citizens with the opportunity to spread their risks among a large community while allowing legitimate businesses to earn a profit. When insurance policies rely more on risks of only a few individuals or small groups, this social function is lost. The ability to identify and exclude high-risk individuals can result in the paradoxical situation of insurance being most easily available to those who need it the least. With regard to health insurance, this problem is accentuated when the cost of insurance is borne primarily by employers and is particularly true in small businesses whose profits and even survival may be threatened by serious illness in a few employees.

Insofar as this is a social problem, it is not solely the responsibility of the insurance industry to ensure access to health care for all (Kass 1992; Murray 1992). This tension between the legitimate business goals of the private insurance industry and the social need for universal access to health care has accelerated public pressure for a national policy that will reconcile the two goals.

## The Problem of Defining Genetic Conditions and Tests

Definitions can become important when insurance policies and laws distinguish genetic conditions and genetic tests from other medical conditions and tests. While some conditions (e.g., Tay-Sachs disease) have a virtually purely genetic basis, most genetic disorders involve an interaction between a genetic predisposition and environmental factors. Even single-gene disorders (e.g., sickle-cell disease and cystic fibrosis) have variable expression depending in part on such environmental factors as oxygen tension in the former and nutritional factors in the latter.

Similarly, some tests, such as those involving mutation analysis, might seem to be clearly genetic tests, but many others, used to test for genetic disorders, measure gene products or further-removed effects. The latter include many tests that could be considered genetic tests, such as Guthrie spots, which test for elevated levels of phenylalanine, or any X-ray used to diagnose or rule out achondroplasia. The point of these observations is that there is no clear boundary between genetic and nongenetic conditions and tests.

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0002-9297/95/5601-0042$02.00

## Implication for Different Types of Insurance

Medical assessment, including the use of genetic information, is often used in underwriting of health, life, and disability insurance, but the nature of the assessment and the principles of underwriting vary for each type of insurance product. In social policy terms the need for basic health care and disability income replacement is quite different from the need for life insurance. These differences should be considered when one is discussing the implications of genetic testing of insurance applicants.

### *Health Insurance*

The practices of insurers regarding reimbursement for genetic testing and services, including counseling and treatment, are usually explicit in policies when they are issued. In general, reimbursement for testing is provided when the test is "medically indicated," usually requiring that the patient be symptomatic. Genetic testing *might* also be considered to be indicated if there is a positive family history for the condition in question. This standard will become increasingly problematic with the development of new tests that arguably should be offered to the public or a large subpopulation. Present examples include phenylketonuria testing of newborns, Tay-Sachs testing of Jewish individuals of Ashkenazic descent, and sickle-cell testing of African Americans.

Reimbursement practices are affected by standard medical practices. A recommendation by a professional society that a test is indicated under specified circumstances will influence insurance policies on reimbursement. In general, insurance companies look to health professionals for guidance as to whether a test is medically indicated.

In addition to reimbursement for laboratory tests, clinicians and patients are also concerned about reimbursement for pretest and posttest counseling. It is generally acknowledged that reimbursement for counseling is inadequate. Widely accepted guidelines for genetic testing emphasize the necessity of education and counseling so that people can make informed choices on whether to be tested, as well as informed choices regarding reproductive (and other) decisions, particularly if a test result is abnormal (Committee on Assessing Genetic Risks 1994).

A more serious question is whether insurers would pay for medical services or deny coverage to patients whose genetic disease could be classified as a preexisting condition. Considerable ambiguity exists in characterizing an individual who has been found to have the allele for Huntington disease. Some would argue that he or she only has the predisposition to develop the condition at a later time. An insurer, however, might argue that the condition is present, albeit in latent form, as soon as the individual acquired — or knew that he or she had acquired — the abnormal gene.

Insurance company policies on these matters will obviously affect individuals' willingness to be tested. Adverse policies could discourage individuals from seeking testing and thereby could deprive them of the opportunity of either obtaining timely treatment or making reproductive choices that might, in the long run, both improve health and reduce the cost of health care for the insurer and others. Such practices could also discourage patients from volunteering for research studies involving genetic testing.

### *Life Insurance*

Approximately 70% of adults have some form of life insurance. Some of these are group policies with little or no medical underwriting, but approximately three-quarters are purchased individually. The amount of information sought depends in part on the amount of coverage for which an individual applies. Approximately 97% of all applications for ordinary life insurance are accepted, while 3% are rejected. Of those accepted, <5% are required to pay higher than standard premiums (Morton 1984).

### *Disability Insurance*

Disability income insurance pays the policyholder a portion of his or her income in the event of illness or injury. Such policies vary in several regards, including how long before payments begin, how long payments continue, the extent to which the disability must incapacitate the individual, and whether the individual must be able to work at all or simply not be able to work at his or her usual occupation.

Types of disability insurance include Social Security Disability Insurance, group policies, life insurance riders, workers compensation for job-related disability, and individual policies. Since there are many more conditions that disable rather than kill, and since the amount of payout is often much larger, the standards for writing disability insurance are much stricter than those for life or health insurance. Applications are therefore more likely to generate deeper inquiries into medical background and, possibly, to elicit more testing.

## Ethical and Policy Questions

### *Risk Classification*

Distinguishing and classifying individuals at different risks is at the heart of commercial insurance as it is practiced today, particularly when individual and small group policies are involved. Insurers do not believe that genetic conditions — or genetic tests that predict illness, death, or disability — should be excluded from this traditional practice. Differentiation of applicants on the basis of health risks is legal and should be distinguished from discrimination, which is illegal if based on race, gender, or sexual orientation.

The extent of such legal discrimination at present is not clear, nor can its future course be predicted with any clar-

ity. There have been reports of denial of coverage on the basis of genetic information (Billings et al. 1992), though some have questioned the validity of many of these claims (Lowden 1992).

At present it appears that insurance companies do not require genetic tests, particularly molecular tests, in underwriting. This is partly because of both the rarity of most genetic disorders and the high cost of such tests, as well as unfamiliarity with their validity and usefulness in the insurance setting. However, "multiplexing" of tests could result in marked reductions in cost, so that genetic testing could become as commonplace as multiphasic chemistry tests or multiple tests on a urine sample. Although insurers may not now require genetic testing, they nevertheless do make decisions based on genetic information, including family history or prior diagnostic tests performed in the course of delivery of medical care to the applicant and his or her family.

Information may be obtained from an application form, a medical record, or other sources, such as the MIB (1993). This is a nonprofit cooperative agency formed by member insurance companies to combat fraud. It consists of a large database of insurance applicants identified by name, birth date, and state. A series of codes describes broad classes of medical impairments with qualifying dates and sources of information included in each file. Governed by a strict code of regulations, the MIB provides a service to underwriters and is used only during the underwriting of new applications. Member companies can only access the data during the application process and only with the consent of the applicant. Insurers can access the database only to confirm that they have reviewed the same relevant information on the medical history of the applicant that has been collected by their competitors. The information cannot be used to directly rate or deny insurance to an applicant; it can be used only as a guide to further investigation by the requesting company. MIB information is purged after 7 years.

Although many diseases are clearly genetic or have a significant genetic component, MIB codes include only a few genetic diseases (e.g., cystic fibrosis and hemophilia), while most would be coded under rather obscure general categories. Huntington disease, for example, is coded as "disorder of the central nervous system for which there is no specific code." The same code is used for amyotrophic lateral sclerosis, encephalitis, and Bell palsy. There are no listings for heterozygotes for recessively inherited conditions.

The availability of insurance will also be affected by the definition of "preexisting conditions," since health insurance and disability insurance policies commonly exclude coverage for such conditions. It could be argued that a person found to be carrying a gene, even though not symptomatic until late in life, has had the "condition" since birth. A different definition of "preexisting," closer to the common understanding of the term, would center on previously diagnosed or treated conditions.

The possibility that information concerning an individual's genetic status could be used to determine "insurability" or premium rates is likely to alter standards of informed consent for genetic testing. The very high value placed on autonomy in medical decision making requires that individuals be informed of risks reasonably to be expected before they decide whether to undergo a medical procedure. Denial of health insurance, in particular, can be a catastrophic event. If there is a reasonable risk of such denial, those responsible for obtaining consent to testing ought to disclose it.

Concealment of medical information (genetic or otherwise) by health-care providers is an important issue. If an insurer is considering a claim and finds that the attending physician has not disclosed all the medical information in the report submitted with the application, the claim may be denied. In authorizing the attending physician to report to the insurer, the applicant signs a waiver that usually says that all "pertinent information" should be sent. If the insured becomes ill or dies and an omission of information is uncovered, the insurer may rescind the policy and return the premiums but not honor the claim. The attending physician may then be at risk of a litigation initiated by the insured (whom the physician was originally trying to protect).

### *Adverse Selection*

Adverse selection occurs when individuals have more information about their risk of illness than do insurance companies—and base their insurance-purchasing decisions on such information. The imbalance allows these individuals at higher risk to buy more insurance yet pay no more than those at lower risk. This may jeopardize the economic well-being of the insurance company or require companies to raise all premiums, as protection against adverse selection. The latter approach imposes costs on others who are not at higher risk. In addition to the deception involved, this seems to conflict with the current practice in our society—that the cost of insurance should be higher for those at higher risk.

Adverse selection poses a greater problem for life and disability insurance than for health insurance, since the latter is less discretionary. Health insurance is typically obtained through groups, whereas life and disability insurance are more commonly obtained through an individual application. In addition, few individuals can afford to forgo health insurance and will therefore generally pay higher premiums.

Some would argue that the basic premise of charging more for those at higher risks is ethically flawed. According to this view, genetic conditions are never the individual's "fault" and should therefore never be the basis for insurance discrimination. Insurers, on the other hand, will point out that a brain abscess or subacute bacterial endocarditis is also not an individual's fault but nevertheless is

a condition that increases an applicant's risk and might warrant a premium rating. The basic principle of pricing commercial insurance states that risks are spread among a group of equals. Persons at higher risk are placed in a higher (more costly) pool. Critics of the health insurance industry emphasize the inequality of the present system, which allows companies to practice "adverse rejection"—i.e., to discontinue coverage when a client, who has been faithfully paying premiums, is found to have a serious condition. It is to be hoped that health care–reform legislation will eliminate this inequity.

Genetic counselors must be cautious about the problem of adverse selection. A vigorous position of patient advocacy might lead a practitioner to tolerate or even advise a patient on how to maximize the benefits of genetic testing without risk of losing insurance or paying higher premiums. Others would oppose such a position, not only because of the deception involved if important information is withheld from insurers, but because they advocate cooperation between insurers and providers as the best way to achieve fair and reasonable policies in the long run.

### *Confidentiality*

The central role of confidentiality in health care has been recognized since Hippocrates and has been reinforced repeatedly in contemporary writings and in the law. Patients will not be able to maximize the benefits of health care unless they feel secure in disclosing potentially embarrassing and stigmatizing information about themselves. Such trust is essential if the doctor is to obtain the information needed to provide competent care, and it is generally in society's interest for patients to seek medical help for health problems, whether they are infectious or genetic conditions that may present risks to others or are disabilities that interfere with leading full and productive lives.

Like all principles, respect for confidentiality must have exceptions. Reporting of infectious diseases to state health departments and reporting of child abuse to appropriate agencies are such examples that are widely accepted, justified by the risk of harm that is preventable through state action. Some jurisdictions have held psychotherapists liable for not warning an identifiable victim of a patient's violent plans (Tarasoff v. Regents of the University of California 1976). These debates involve complex questions of whether a geneticist has a right or a duty to disclose genetic information to a relative without the consent of the patient.

Disclosure of stigmatizing information in the absence of consent may occur during the claims process when an insurance company exchanges information with an employer, particularly in the case of small companies. Similarly, during underwriting, physicians commonly release an entire medical record to an insurer, thereby disclosing genetic information even though it was not specifically requested.

## Legal Issues

For 5 decades the regulation of insurance practices has been handled largely by state, not federal, law. Some states recently have enacted legislation that prohibits discrimination based on genetic conditions. The state laws vary, however, in whether they apply to all genetic conditions or only to certain enumerated ones.

The Employee Retirement Income Security Act (ERISA), a federal law that regulates pension and benefit plans, does have significant impact on access to insurance. Section 514 of ERISA preempts state insurance laws from regulating self-insured health-benefit plans (Metropolitan Life Insurance Company v. Massachusetts 1985). This includes mandated benefits, antidiscrimination, high-risk pools, and other provisions.

In McGann v. H & H Music Co. (1991), the employer had purchased a commercial group health insurance policy that provided for lifetime medical benefits of $1 million for all employees. Soon after Mr. McGann submitted his first claims for reimbursement under the policy, for treatment of AIDS, the employer canceled the policy, became self-insured, hired the same commercial insurer to serve as the claims administrator for the new plan, and reduced the maximum lifetime coverage for AIDS to $5,000 while retaining the $1 million limit for all other medical conditions. In a controversial decision, the U.S. Court of Appeals for the Fifth Circuit held that the employer was within its rights to amend the plan at any time and therefore did not violate the antidiscrimination provision of ERISA.

The Americans with Disabilities Act (ADA) prohibits employment discrimination on the basis of disability. It applies to private-sector employers with $\geq 15$ employees. The ADA does not prohibit an employer or an insurance company from underwriting risks, classifying risks, or administering the risks of a bona fide plan. The statute permits an employer not subject to state insurance laws (i.e., a self-insured employer) to establish and administer the terms of a bona fide benefit plan. Thus, especially as to self-insured employers, differences in coverage or benefits for genetic conditions are lawful. The reach of the ADA will be decided over the years, in appellate courts, and therefore it is not clear to what extent it might regulate the use of genetic information by employers or insurers.

## Summary

The rapid expansion of opportunities for genetic testing has been accompanied by complex questions about the appropriate relationships between providers, patients, and insurers. Some of these questions involve large public-policy decisions, such as whether the government should guarantee access to health care for all citizens. Universal access to health care, without regard to past, present, or future risk of disease, could eliminate risk-oriented un-

derwriting in health-care coverage. A positive response to that question will ameliorate other problems.

Until universal access is reality, genetic testing and genetic diagnosis will raise important issues for the practicing geneticist. How much does a client need to know about insurance implications before consenting to a genetic test? Should patients be counseled to purchase insurance before being tested? Should genetic information be excluded from medical records before their release to insurance companies for routine reimbursements or underwriting? What are the ethical and legal responsibilities of the geneticist?

## Acknowledgments

This document was drafted by the ASHG Ad Hoc Committee on Insurance Issues in Genetic Testing. Committee members are L. Andrews, American Bar Association, Chicago; B. Bowles Biesecker, Department of Molecular and Medical Genetics, University of Michigan, Ann Arbor; N. Fost, Department of Pediatrics and Medical Ethics, University of Wisconsin, Madison; L. G. Jackson, Department of Medicine, Division of Medical Genetics, Thomas Jefferson University, Philadelphia; N. Kass, Johns Hopkins University, Baltimore; J. A. Lowden, Crown Life Insurance Company, Regina, Saskatchewan; T. H. Murray, Center for Biomedical Ethics, Case Western Reserve University, Cleveland; J. Payne, Health Insurance Association of America, Washington, D.C.; P. R. Reilly, Shriver Center, Waltham, MA; and M. A. Rothstein, University of Houston Law Center, Houston.

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