Am. J. Hum. Genet. 52:565–577, 1993

Insurance and Genetic Testing: Where Are We Now?

Harry Ostrer,* William Allen,† Lee A. Crandall,† Ray E. Moseley,† Marvin A. Dewar,† David Nye,‡ and S. Van McCrary†

*Human Genetics Program, Department of Pediatrics, New York University Medical Center, New York; †Medical Humanities Program, Department of Community Health and Family Medicine, College of Medicine, and ‡Florida Insurance Research Center, School of Business Administration, University of Florida, Gainesville

Summary

Basic research will spur development of genetic tests that are capable of presymptomatic prediction of disease, disability, and premature death in presently asymptomatic individuals. Concerns have been expressed about potential harms related to the use of genetic test results, especially loss of confidentiality, eugenics, and discrimination. Existing laws and administrative policies may not be sufficient to assure that genetic information is used fairly. To provide factual information and conceptual principles upon which sound social policy can be based, the Human Genome Initiative established an Ethical, Legal, and Social Issues Program. Among the first areas to be identified as a priority for study was insurance. This paper provides a review of life, health, and disability insurance systems, including basic principles, risk classification, and market and regulatory issues, and examines the potential impact of genetic information on the insurance industry.

Introduction

Researchers will develop new genetic tests capable of predicting risk of disease or disability and risk of premature death in presently asymptomatic individuals. Basic research in human genetics, funded by the Human Genome Initiative (HGI) and other sources, will spur development of such tests. Proponents of presymptomatic genetic testing deem it beneficial because of the opportunities to prevent or delay the onset of illness, to treat the early stages of disease more effectively, or to provide more informed reproductive decision making.

Although information from predictive tests offers clinical benefits, experts have expressed concerns about potential harms, such as intrusions on privacy and confidentiality, inaccurate prediction, and discrimination in insurance and employment (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research 1983; U.S. Congress Office of Technology Assessment 1988*a;* Nelkin and Tancredi 1990; Holtzman and Rothstein 1992). Currently, only a limited number of tests exist, and most of these tests have high predictive value. Although the future may bring a substantial increase in both the number of predictive genetic tests and the volume of genetic information, the predictive values for some of these tests may be lower than those of tests currently available (McKusick 1991). Therefore, existing regulations and guidelines for genetic information, premised on a limited number of tests with high predictive value for disease and carrier status, may prove inadequate for avoiding harms from use of this newly acquired body of information.

Concerns about confidentiality of information, eugenics, and unfair discrimination based on test results have led some to propose either (*a*) moratoria on genetic testing or (*b*) more restrictive guidelines for either genetic screening or the use of genetic information (Pennsylvania Senate Resolution no. 75, 1991; and California Assembly Bill 1888, 1991). Because laws and regulatory policies require a clear understanding of the ethical, legal, and social issues to be effective (Crandall and Moseley 1991), the HGI established an Ethical, Legal, and Social Issues Program (ELSI) to provide fac-

Received January 31, 1992; final revision received December 1, 1992.

Address for correspondence and reprints: Harry Ostrer, M.D., Human Genetics Program, New York University Medical Center, 550 First Avenue, MSB-136, New York, NY 10016.

0002-9297/93/5203-0014$02.00

tual information and conceptual principles upon which sound public policy can be based (Juengst 1991).

ELSI identified insurance as a priority for study, because current practices for providing life, health, and disability income insurance are almost certain to be affected if there is rapid growth in predictive testing and an attendant increase of new predictive genetic information about potential consumers. In this paper we describe the basic premises and principles upon which insurance is based, outline the methods currently used by insurance companies for risk classification, and note market conditions that affect the provision of insurance. We then address the present and potential impact of genetic information on the insurance industry. We also review current federal and state laws that bear on the use of genetic information in insurance underwriting and in provision of health-care benefits. Finally, we elucidate some of the questions that must be analyzed if constructive policy responses are to be developed to address the effects that predictive genetic testing have on insurers, health-care financiers, and consumers.

Insurance Underwriting

Insurance (life, disability, and health) provides individuals with protection against unexpected losses, by transferring risk of loss to an insurance company. From a societal standpoint, "insurance is an economic device for reducing and eliminating risk through the process of combining a sufficient number of homogeneous exposures into a group in order to make the losses predictable for the group as a whole" (Vaughan 1992). Homogeneous risks are those with the same or similar chance of loss; hence, insurance transfers the risk of loss from the individual to the group, among whom there should be a sharing of losses on some equitable basis.

Insurers use the term "underwriting" to refer to their decisions on (1) whether to reject or accept the risk of loss, and, if the risk is accepted, (2) how to classify the risk, in order to set premiums based on reasonable expectation of loss. The basic approach to underwriting decisions varies according to the setting in which it is sought and provided. Three basic approaches are (1) *individual underwriting,* in which each individual applicant for coverage is assessed, to determine his or her individual risk of loss and amount of premium; (2) *experience-rated underwriting,* in which entire groups (usually occupational) are assessed for their risks of loss, with premiums based on actual experience of the group's previous losses; and (3) *community-rated underwriting,* in which all policyholders' premiums are uniform, based on the expected loss for a geographic area.

Risk classification refers to the process of categorizing insurance applicants according to their likelihood and magnitude of loss. Through this process, risks with the same or similar exposure to loss are grouped, and a price is set (Moseley et al. 1991). From an economic viewpoint, risks may be treated as homogeneous if the process for segmenting them costs more than assuming that they are the same (Pokorski 1992).

Each insurance company maintains its own handbook of recommended risk-assessment practices. One guide available to all insurance companies is *Medical Risks: Trends in Mortality by Age and Time Elapsed,* a reference that is sponsored by the Association of Life Insurance Medical Directors of America and by the Society of Actuaries (Lew and Gajewski 1991). Underwriting decisions about rarely encountered health conditions, however, are not likely to be supported by actuarial data and may be handled in an ad hoc fashion by insurance companies, according to their individual corporate policies (personal meeting with medical directors of life insurance companies, March 26, 1992).

Successful risk classification depends on access to all relevant and available information. The potential insured may possess information about personal and family medical history critical to risk classification. Insurers have a vital interest in obtaining such information and in ensuring its accuracy. In addition to legal remedies for fraud or misrepresentation in the insurance application process, the insurance industry has developed an elaborate system that alerts underwriters to factors in an applicant's prior application(s) that may have been omitted or concealed in the current application.

The Medical Information Bureau (MIB), a nonprofit association of more than 800 insurance companies, serves as a clearinghouse through which insurers considering an applicant can detect possible inconsistencies, irregularities, or omissions in the information submitted by an individual in applications to other companies. The MIB does not possess an individual's entire medical record. Member companies must submit to MIB a coded report summarizing relevant factors discovered about applicants for life and health insurance. Although such information consists primarily of medical conditions, nonmedical information such as dangerous avocations or adverse driving records must also be included, if confirmed. Information concerning amounts of insurance issued, as well as underwriting and claims decisions, cannot be reported (Latrenta 1990).

A member company considering an applicant may access this coded information as a check on the applicant's truthfulness or accuracy. Information obtained from the MIB is intended to serve merely as a warning, indicating possible inconsistency or omission and the need for further inquiry or testing of the applicant. MIB asserts that its reports are not used to deny coverage or to issue a substandard classification solely on the basis of information obtained from the MIB. Underwriting decisions are supposed to be based on the insurer's own independent inquiry (Latrenta 1990; U.S. Congress Office of Technology Assessment 1992). A minority of states prohibit insurers from basing underwriting decisions on MIB reports alone (U.S. Congress Office of Technology Assessment 1992). In addition, the Federal Fair Credit Reporting Act requires insurers to disclose to consumers, on written request, the nature of information, such as MIB reports, if an adverse underwriting decision has been based on reported information (15 U.S.C. §1681 m.). Individuals may access their MIB files, and procedures exist for challenging and correcting inaccurate information (Latrenta 1990). Of more than 41,000 requests for disclosure of MIB records in 1991, 815 individuals challenged the accuracy of their MIB records, and the MIB altered 399 of these disputed records (Medical Information Bureau annual report 1991).

Insurance Markets

Insurance markets arise and persist only under certain conditions. Individuals typically demand insurance when they recognize a significant risk of incurring a financial loss that they are unwilling or unable to bear. Private firms are willing to supply insurance if they perceive that a profit can be made on the transaction. Depending on individual preferences, there is some maximum price above which the individual will not purchase insurance. Similarly, there is a minimum premium that the insurer must receive in order to be willing to supply insurance. As long as these prices overlap, an insurance market will exist, with the attendant opportunity for risk spreading noted elsewhere (Moseley et al. 1991).

Insurance companies do not accept all risks. In order to find a risk acceptable, insurers ideally require a sufficient number of homogeneous risks, a definite and measurable loss, an estimate of fortuitous loss, and a paucity of catastrophic losses (Rejda 1992, p. 24). In addition, insurers wish to avoid or, at least, minimize the effects of providing coverage for risks about which the potential insured possesses relevant information not available to the insurer.

Insurers are concerned about "the tendency of the persons whose exposure to loss is higher than average to purchase or continue insurance to a greater extent than the remainder of the group," a phenomenon they call "adverse selection" (or "antiselection") (Vaughan 1992). In health insurance, for example, a nationally representative survey by the Agency for Health Care Policy and Research found that the "presence of chronic conditions or other serious health problems or functional limitations increased the likelihood of wanting to purchase private health insurance" (Beauregard 1991). Applicants for insurance may possess, without the intentional misrepresentation or deception involved in fraud, relevant risk information not available to the insurer. Thus, the problem of adverse selection extends beyond the problem of fraud.

The rate of fraud in insurance applications, however, is one indicator of the potential magnitude of adverse selection. Saliva tests used to detect cotinine are positive in 5%–30% of applicants who claim to be nonsmokers in order to gain preferred risk classification (personal meeting with medical directors of life insurance companies, March 26, 1992). Another measure of fraud is in the number of cases in which major life insurance companies successfully defended the denial of benefit claims in court. In these cases the companies demonstrated that, at the time of application, the insured had knowledge of the preexisting condition that caused death (personal conversation with medical director of life insurance company, July 14, 1992). On the basis of this measure of claim denials that are successfully defended within the 2-year exclusionary period, fraudulent disability-income insurance claims may be as high as 7% (personal conversation with director of disability income insurance program, May 26, 1992). Insurers fear that, if a significant number of those most likely to make claims misrepresent or fail to disclose information necessary for accurate risk assessment and calculation of premiums, the premiums will not cover the larger than expected losses. Some insurers suggest that such a scenario could lead to increased premiums for all policyholders or, if severe enough, to company insolvency (Mehr and Gustavson 1987, p. 494; Pokorski 1992).

In their opposition to legislative restrictions on the use of genetic test information in underwriting, insurance representatives have alleged that routine prohibition of insurer access to risk factors known by applicants (such as HIV status or genetic predisposition to

disease) could result in widespread adverse selection and an "assessment spiral phenomenon" potentially resulting in market dissolution (Pokorski 1992). The market-dissolution scenario assumes that premium increases, necessitated by unexpected losses resulting from widespread adverse selection, would ultimately exceed the rates that standard and preferred-risk policyholders are willing to pay. This assessment of higher premiums would encourage low-risk applicants to buy from another insurer or to leave the insurance market completely. The exit of lower-risk persons from the risk pool would increase the proportion of high risks remaining in the pool of insureds. The increasing proportion of higher risks in the pool of insureds would engender a spiraling cycle of further increases in premiums, the continued exit of better risks, and eventually market dissolution, including the exit of some companies from the market, because of lack of potential for profit. Supporting examples of this assessment spiral phenomenon have thus far been limited to casualty lines of insurance (Pokorski 1992). Even short of market dissolution, adverse selection may make insurance markets less robust, by pricing some potential purchasers out of the market.

Life Insurance

Life insurance protects the beneficiary against the premature death of the insured. Policies may be obtained individually or through a group insurance plan. In 1989, approximately 71% of life insurance protection in the United States was purchased on an individual basis and, therefore, was reviewed for health characteristics (American Council of Life Insurance 1990, p. 9). Thus, most applicants for life insurance are assessed individually for their risk of loss, with one of the following results: (1) the applicant is accepted as standard risk (92%); (2) the applicant is charged higher premiums for substandard risk (6%); or (3) the applicant is rejected as uninsurable (2%) (Pokorski 1989). Under certain circumstances, insurers may offer persons classified as standard risks a premium discount based on healthy behaviors that make them "preferred" risks (e.g., nonsmokers).

Depending on the face value of the policy, life insurers may require applicants to undergo medical tests as part of the underwriting process—and may do so more commonly than do health insurers. Life insurers commonly use blood tests to screen for diabetes, hyperlipidemia, renal disease, liver disease, and HIV infection. Life insurers use urine tests to screen for drug and tobacco use, diabetes, and renal disease (American Council of Life Insurance 1990, p. 9). Currently, few tests are used to identify Mendelian diseases or to monitor genetic predisposition to disease. Costs limit the use of medical testing for insurance risk assessment. Some life insurance companies, for example, may not require testing if the face value of the policy is less than $50,000 (personal meeting with medical directors of life insurance companies, March 26, 1992).

Disability-Income Insurance

Disability-income insurance protects the insured against illness or injury that may result in loss of income from his or her occupation. Many of the policies sold in the United States are issued to employer-based groups. Insureds under group policies are not individually assessed for risk. Our review of disability-income policies showed that benefits provided by group policies are offset by the amount of disability benefits the insured receives from other sources, such as pension plans, Social Security Insurance, and other sources.

Individual disability-income policyholders are assigned to rating classes based on age, profession, health status, and avocation. The insurer's ability to change rates and cancel policies can be restricted. Individually acquired policies typically pay approximately 60% of the insured's income if disability prevents performance of current occupation, even if the insured's disability does not preclude other means of livelihood or recreational pursuits. Therefore, insurance companies are often more concerned about adverse selection in disability insurance than in life insurance, because of the substantially greater incentive to make a disability claim (personal conversation with director of disability income insurance program, May 26, 1992). As a result, disability-income insurance policies utilize exclusions from coverage for specific types of disability.

Health-Care Insurance and Benefits

Health insurance provides coverage for medical expenses that result from illness or injury. Some programs also provide coverage for preventive health care. Most health insurance is obtained through employment (Congressional Research Service 1988). More than 90% of firms with 25 or more employees offer some type of employee health-care coverage, through either commercial insurance carriers or self-insured plans. Such coverage may be obtained from not-for-profit organizations (especially the Blue Cross and Blue Shield programs), for-profit insurance companies, health maintenance organizations, or employer or union self-insurance funds. The trend in recent years has been to

provide health benefits through employer self-insured plans. In 1990, 56% of employee health coverage was obtained through such plans (Sullivan and Rice 1991).

Most health insurance or health-care benefits are obtained through group plans, rather than through individual plans. For several reasons, applicants for group health insurance typically are not subjected to individual risk classification. Risk selection and classification of *groups* assess the risk of loss for the entire group, on the basis of previous loss experience of the membership. Employee groups tend to comprise persons healthy enough to work, thus eliminating those high-risk individuals whose poor health prevents employment. Larger groups enjoy the presumption that the total risk for the entire group is close to average. Moreover, the losses that do occur in a large group can be more easily spread over the entire group (Pokorski 1989).

Even though group health insurance does not engage in individual risk assessment, group underwriters take precautions against adverse selection. Group underwriters normally will not insure groups formed primarily for the purpose of acquiring insurance, because of the likelihood that such groups will include more high-risk individuals than will groups formed for other purposes. Since smaller groups have less capacity to spread risks, adverse selection becomes a greater problem as the size of the group decreases (Pokorski 1989). Therefore, insurers protect themselves from adverse selection in smaller groups by more frequent use of restrictions on preexisting conditions, benefit limitations, or exclusion of coverage for particular health conditions (U.S. Congress Office of Technology Assessment 1988*a*).

For individuals and very small groups (fewer than 15 members) insurance companies select and classify risk by means of a health-history questionnaire and a copy of the potential insured's medical record or a statement from the individual's physician. Testing, especially medical testing, is not routinely required by health insurers. Applicants may be classified as standard risks (78%–79%) or substandard risks (15%) or may be denied insurance altogether (6%–7%) (Pokorski 1992). For those classified as substandard risks, the policy may include waivers excluding coverage for a specified high-risk condition, a higher premium, or both (Pokorski 1989). Insurers typically deny coverage to applicants whose probability of disease exceeds three times the average for their age and sex (U.S. Congress Office of Technology Assessment 1988*b*).

Employment-based health insurance mechanisms leave some identifiable groups, particularly the unemployed, with severely reduced options for purchasing health insurance. To address the needs of these groups, other mechanisms of health insurance have been developed. In 1965, the Federal Government mandated state participation in the Medicaid program, to provide health care for the qualified indigent (42 U.S.C.A. §1396 [West 1983]). Medicaid income/eligibility guidelines vary dramatically from state to state. Thus, Medicaid fails to cover large numbers of low-income individuals (Holahan and Cohen 1986). Low-income individuals who do not qualify for the Medicaid program and whose employers do not provide health insurance have the "option" of purchasing coverage on the open market. Many people who have standard risks, however, cannot afford the premium rates. In practice, 31–36 million people in the United States—especially the poor, members of minority groups, young adults, children, and part-time workers—do not have health insurance coverage (Friedman 1991).

Genetic Testing and Potential Effect on Insurance

Human disease often results when thresholds of anatomic or physiological dysfunction are surpassed. Factors leading to human disease include inherited genes, new mutations, and toxic environmental exposure. Genetic risk factors are identified by clinical presentation, family history, and genetic testing (Beaudet et al. 1989).

Genetic tests are a means for identifying those at risk for developing disease with a single gene, chromosomal, or multifactorial etiology. Many genetic tests are based on chromosome analysis or on the activity or concentration of enzymes, serum proteins, or metabolites in blood or urine. More recently, DNA-based tests have been developed for detection of mutations in specific genes. Some of these are screening tests designed to identify individuals at high risk of manifesting genetic disorders. Some individuals with a positive test result will never develop disease. Others may be affected mildly. Determination of any individual's status may require clinical evaluation and, possibly, other tests (Holtzman 1989).

Genetic tests for predisposition to common adult-onset disease, including cancer, atherosclerosis, diabetes, mental illness, and neurodegenerative disease (e.g., Alzheimer disease) may become very common over the next 10–15 years (McKusick 1991). Because these diseases are multifactorial and genetically heterogeneous, a given set of mutations will identify only a

fraction of those at risk for disease. Since several intervening steps may be required in order for disease to develop, the predictive value of a positive test result may be less than that used for previous forms of genetic screening. Indeed, the predictive value of a positive test result may differ for each of the disease processes that is associated with a given mutation. The age at onset of disease may influence the utility of predictive testing for claims experience, since some diseases may occur at a time late in life, when life insurance companies would ordinarily expect to have an increased claims exposure regardless of test results. (Alzheimer disease or prostate cancer in a healthy person are examples.)

Individuals, insurers, employers, and states all have incentives to use information derived from genetic testing, even though many individuals with positive tests will not develop disease. In fact, both the primary value and the greatest danger of such tests may lie precisely in those situations in which assessment of risk can occur long before clinical manifestation and diagnosis of disease are possible. Individuals may seek genetic testing, to reduce, through early identification and intervention, morbidity or mortality of disease. Others may seek testing because knowledge of genetic status may affect reproductive decision making, either prior to conception or after conception (through antenatal detection of fetuses with single gene, chromosomal, and multifactorial disorders).

On the basis of knowledge of their genetic risks, individuals may have an incentive to buy insurance at standard rates or in larger amounts, without disclosing genetic test results to the insurer. Alternatively, individuals who might benefit from presymptomatic detection and treatment of disease (e.g., polycystic kidney disease) may avoid testing, for fear that a positive result might lead either to an increase in insurance rates or to complete or partial denial of coverage for their genetic diseases. On the other hand, individuals who, on the basis of family history of a dominant disease, such as Huntington disease, have been denied insurance, may *seek* testing, because a negative test result would render them insurable.

Insurers may obtain, at the time of underwriting, information about family history, previous medical history, or workplace testing. This information may be obtained directly from an insurance application, the physician's statement, or the medical record. Health insurance companies or self-insured employers may also obtain information about genetic conditions from submitted claims (Council on Ethical and Judicial Affairs, American Medical Association 1991). Currently, insurance companies rarely, if ever, require genetic testing as a condition for underwriting policies (U.S. Congress Office of Technology Assessment 1992).

Insurance companies may benefit indirectly from the advent of genetic testing, because early intervention may increase life span, mitigate or prevent disability, and reduce long-term treatment costs. In addition, insurance companies may benefit directly from genetic-testing information used for risk selection and rating. Many insurers claim they have no plans to initiate or require genetic tests in the foreseeable future. Insurers uniformly insist, however, that they must not be *prevented* from using genetic-testing information already in the medical record, to assess risk of candidates for initial coverage, renewal, or increased coverage, in order to protect the companies and other policyholders from the results of adverse selection (Report of the ACLI-HIAA Task Force on Genetic Testing 1991).

Individuals identified, by genetic tests, to be at increased risk for larger or premature claims might be charged higher premiums, denied coverage for certain conditions, or even denied insurance altogether. On the other hand, insurers that already offer preferred-risk premiums to individuals who avoid unhealthy behaviors, such as tobacco use or substance abuse, might also offer preferred-risk premiums to persons who have less than average genetic risk of disease. Similarly, insurers may offer a standard risk classification to persons who engage in healthy behaviors shown to mitigate the higher risk of their genetic predisposition to disease, especially if compliance can be monitored. Employers who sponsor health benefits for their employees may have an incentive to use genetic screening to eliminate job applicants, current employees, or coverage of certain diseases that otherwise would increase costs of employer-funded insurance and benefit programs (Council on Ethical and Judicial Affairs, American Medical Association 1991).

Governments may encourage genetic testing because early identification and intervention may reduce the public burden for disorders associated with mental retardation or increased morbidity. In addition, governments will be affected by genetic testing when private insurers or employers exclude coverage for individuals with newly identified genetic risk factors (or when they charge such persons de facto exclusionary rates), because the demand for public insurance of all types will increase. Moreover, many federal, state, and local governments are significant *consumers* of insurance for employee benefits or are themselves self-insurers. In either case, governments may be burdened or benefited by

increased availability of genetic information, in the same way as private employers and insurers are.

Genetic information may be used erroneously. Published reports describe individuals who, on the basis of genetic test results that do not significantly increase the prospect of morbidity or mortality (e.g., hemoglobin S heterozygosity), were denied insurance. The frequency of these events is unknown (Gilbert 1986; Billings et al. 1992).

Legislation Affecting Genetic Information, Insurance, and Health Benefits

The federal government leaves regulation of the insurance industry primarily to the states, with federal law largely reserved to prevent antitrust violations and to exempt self-insured employers from state regulation (McCarran-Ferguson Act; 15 U.S.C.A. §1013 [a]–[b] West 1985). Originally, the primary purpose of state insurance regulation was to assure the solvency of insurance companies and to protect consumers from fraudulent insurance practices (Harnett and Lesnick 1990). Later, regulation was expanded to protect consumers from unequal rates resulting from selective rebates by agents (Wortham 1985). In recent years some states have expanded insurance regulation to address other issues, such as cancellation and renewal of policies and mandatory minimum benefits. The lack of uniformity among the insurance regulations in various states has been mitigated, but not eliminated, by the National Association of Insurance Commissioners (NAIC). Although it has no official governmental authority, the NAIC provides a forum for the development of model statutes and regulations that may be adopted by individual states.

Federal Legislation Affecting Insurance and Health-Care Benefits

Since regulation of insurance has been left primarily to the states, no federal insurance law exists to regulate insurance uses of genetic information. Federal law, however, does provide some protection of employment rights and benefits, which may have implications for the use of genetic information by employers who provide employee group insurance and health-care benefits. Both the Employee Retirement Income Security Act of 1974 (ERISA) (29 U.S.C. §§1001–1381 [West 1985]) and the Americans With Disabilities Act of 1990 (ADA) (42 U.S.C.A. §§12101–12213 [West 1991]) potentially apply to employer uses of genetic information (Gostin 1991).

ERISA exempts employee-benefit plans from state law and regulation, in the interest of national uniformity (29 U.S.C. §1144 [a] [1988]). Because many employee-benefit plans include insurance, ERISA specifies that federal exemption of benefit plans from state regulation does not invalidate the states' traditional regulation of insurance (29 U.S.C. §1144 [b] [2] [A] [1988]). In order to prevent states from using traditional insurance regulation as a guise to attain regulatory control of employee-benefit plans, ERISA prohibits states from merely "deeming" employee-benefit plans to be insurers (29 U.S.C. §1144 [b] [2] [B] [1988]).

Out of the ensuing litigation to determine how state insurance regulation relates to employee-benefit plans, a crucial distinction has emerged between plans that self-insure and plans in which employee risks are directly underwritten by commercial insurers. Courts have concluded that state insurance regulation, such as minimum health-benefit mandates, does not apply to self-insured benefit plans (*Metropolitan Life Ins. Co. v. Massachusetts,* 471 U.S. 724, 732 [1985]). Employee-benefit plans in which the risk of employee loss claims is directly underwritten by an insurer, however, remain subject to state insurance regulation (*FMC Corp. v. Holliday,* 111 S. Ct. 403, 409 [1990]). This distinction between self-insured employers and those who do not self-insure results in substantial disparity.

Self-insured employers are not subject to state insurance taxes, state unfair-discrimination statutes, minimum-benefit requirements, or mandated contributions to state health insurance pools for commercially "uninsurable" risk pools. Therefore, self-insured employers can change their employees' coverage, benefits, or excluded health conditions in ways that state law might prohibit in commercially insured health-care plans. For example, the U.S. Court of Appeals Fifth Circuit recently held that the ERISA preemption allowed a self-insured employer to reduce maximum medical benefits from $1,000,000 to $5,000 for employees who contract AIDS (*McGann v. H&H Music Co.,* 946 F.2d 401, 405–408). The U.S. Supreme Court declined to hear an appeal of this case, thereby letting this holding stand.

Although ERISA exempts self-insured employers from state regulation, it does provide limited protection against certain forms of discrimination in employee benefits. Section 510 of ERISA prohibits employers from (1) discharging an employee, (2) preventing an employee's promotion, (3) retaliation against employees who make or litigate a claim, or (4) any other act designed to inhibit or dismiss an employee simply because he or she poses a risk of higher health-care-

benefit claims (29 U.S.C.A. §1140 [West 1985]). In order to prove that an employer has violated these protections, the burden rests on the employee to demonstrate that the employer acted with specific intent to deprive him or her of benefits (*Simmons v. Wilcox,* 911 F.2d 1077). Proving that the employer's motivation was to reduce exposure to benefits claims can be very difficult, because it is relatively easy for employers to defend against discrimination claims—by alleging that plausible business reasons, rather than intent to deny an employee benefits, informed their actions (*Dister v. Continental Group, Inc.,* 859 F.2d 1108, 1111–12, [2d Cir. 1988]; and *Lawford v. New York Life Insurance Co.,* 739 F. Supp. 906, S.D.N.Y. [1990]).

Not only is it difficult to prove the discrimination prohibited by ERISA section 510, but the interpretation of section 510 upheld in *McGann v. H&H Music Co.* does not prohibit discrimination among diseases covered by the benefit plan. Although ERISA prohibits employer actions against an employee because of that employee's risk of higher health-benefit claims, the act does not prevent an employer from selective exclusions or curtailment of coverage in the *entire* employee-health-benefit package, which would accomplish substantially the same goal: of reduced claims.

> ERISA does not broadly prevent an employer from "discriminating" in the creation, alteration, or termination of employee benefits plans; thus, evidence of such intentional discrimination alone cannot sustain a claim under section 510. That section does not prohibit welfare plan discrimination between or among categories of diseases . . . . It does not prohibit an employer from electing not to cover or continue to cover AIDS, while covering or continuing to cover other catastrophic illnesses, even though the employer's decision in this respect may stem from some "prejudice" against AIDS or its victims generally. The same, of course, is true of any other disease and its victims (*McGann v. H&H Music Co.,* 946 F. 2d 401, 407–408).

Self-insured employers are free, therefore, to exclude particular genetic disorders from coverage for all employees or to place inadequate maximum claims limits on them (as H&H Music Co. did in the instance of AIDS). In fact, ERISA does not require (and prevents states from requiring) self-insured employers to provide *any* particular health-care benefits at all (*Shaw v. Delta Airlines, Inc.,* 463 U.S. 85, 103 [1983]).

ERISA does not prevent employers motivated to reduce health-care-benefit expenses from using information from medical testing of employees in determining how to reduce their risk exposure. Moreover, even without medical testing, self-insured employers can gain access to substantial amounts of medical information (potentially including genetic information) about employees, by reviewing claims submissions. Finally, ERISA protects only current employees from discrimination in the distribution of benefits. ERISA does not protect job *applicants,* whose genetic information might prompt employers to avoid hiring them, in order to eliminate potential health-care claims.

Attention has been focused on the potential effect of the ADA on the use of genetic information by insurers, employers, and health-care providers (Gostin 1991; Natowicz et al. 1992). Under the ADA, the protection against discrimination on the basis of disability, which had been applied to federal employers, contractors, and grantees by the Rehabilitation Act of 1973 (29 U.S.C.A. §§701–794 [West 1985]), has been extended to *private* employers. Among other things, the ADA protects persons with disabilities from discrimination in private employment settings, including discrimination arising from such employee benefits as insurance. Disability is defined broadly and includes (1) physical or mental impairments that substantially limit a major life activity, including anatomic loss or disfigurement or mental disorder, (2) a record of such impairment, or (3) one who is "perceived" as having such an impairment (42 U.S.C.A. 12102 [West 1991]).

The ADA explicitly states that underwriting, classifying, or administering risks by insurers or employers is not prohibited by the act. This disclaimer is immediately followed by the admonition, however, that underwriting may not be used as a ruse for otherwise prohibited employment discrimination (42 U.S.C. 12201 §501 [c]). An employer seeking to distinguish legitimate risk selection and classification from prohibited discrimination must make an informed guess based on the congressional intent discernible from the legislative history of the ADA. More definitive legal interpretation of the limits of legitimate risk selection and classification must await the development of case law.

In its deliberations, the House Committee on Education and Labor concluded that the ADA would not prevent life, health, or other insurers from assessing disability as a risk factor, so long as "refusal, limitation, or rate differential (of coverage) is based on sound actuarial principles or is related to actual or reasonably anticipated experience" (HR101-485 [II], p. 137). Moreover, the committee specified that the ADA neither removes the ERISA exemption from state regulation enjoyed by self-insurers nor preempts the application of state laws to commercially insured benefit plans (HR101-485 [II]).

According to the committee, the ADA's admonition against using underwriting as a subterfuge for prohibited discrimination includes (1) denial of a job to an applicant whose disability either is not covered by or would increase the costs of the employer's insurance plan; (2) coverage limits or rate differentials based on disability, without actuarial justification or reasonably anticipated experience; and (3) denial of coverage for conditions unrelated to a preexisting condition that has been excluded from coverage (HR101-485 [II], pp. 136–137).

Although the ADA prevents employers from denying a job to an individual applicant on the basis of a disability that would increase the employer's insurance costs, the act does not prevent employers or insurers from structuring benefit packages for *all* employees that exclude coverage, severely limit coverage, or increase deductibles or copayments for disabilities that reflect an increased risk of loss. Neither does it address whether preexisting conditions that legally may be excluded from coverage include presymptomatic indications of genetic risk. Thus, for *current* employees, the ADA does not provide a substantial increase in protection of insurance benefits over that already entailed in ERISA. The ADA does, however, extend to job *applicants* with disabilities some protection of benefits similar to that which ERISA provides for current employees only.

The ADA provides no *direct* prohibition of the use of genetic or other medical information in underwriting risk. The act's most significant effect on underwriting risk may be the indirect impact of its restrictions on health inquiry and medical testing of job applicants and employees. To the extent that the ADA restricts employers' opportunities to discover employees' and applicants' disabilities, including genetic conditions, the act limits an employer's or insurer's ability to use such information in underwriting.

The ADA prohibits employers from conducting, prior to a job offer, medical assessments to determine whether a job applicant has a disability. Prior to an employment offer, inquiry must be limited to whether an applicant can perform job-related functions. Medical examinations can be undertaken only after a job offer has been made, but the job offer may be conditioned on the results of such an examination. Such medical exams need not be job-related or consistent with business necessity, although criteria used to retract job offers from employees found to have a disability must be job related and consistent with business necessity. Thus, medical testing unrelated to current job performance but useful for anticipating benefit claims is not prohibited (e.g., risk of early-onset cancer or atherosclerosis).

Entrance medical exams may not be conducted unless all entering employees are subjected to the same examination. After a person begins employment, the employer may not compel further medical examination unless it is job related and reflects business necessity. Employers may conduct voluntary medical exams or histories, however, as part of employee wellness or workplace health-promotion programs (42 U.S.C. §12112 [c] [1]–[4]).

The ADA requires information obtained from all such medical exams or inquiries to be maintained separately from other forms and records and to be "treated as a confidential medical record," with exceptions allowed only for managers, first-aid and safety personnel, and government compliance officers, who may be informed of specific medical information when it is relevant to job responsibility (42 U.S.C. §12112 [c] [1]–[4]). Neither the statute itself nor legislative history makes a confidentiality exception for insurers or employers, but the Equal Employment Opportunity Commission (EEOC), the federal agency charged with developing regulations to implement and enforce the ADA, adds a confidentiality exception for both insurers and employers, to the extent that they are underwriting or administering benefit plans. In the Appendix to Part 1630—Interpretive Guidance on Title I of the ADA, the EEOC states that "information obtained in the course of a permitted entrance examination or inquiry may be used for insurance purposes," such as health and life insurance benefit plans, whether self-insured or commercially insured (Fed. Reg. 35739–35752 [July 26, 1991]).

The protection that the ADA offers against genetic discrimination depends on whether genetic conditions are considered disabilities. Gostin (1991) has argued convincingly that presently manifested genetic disorders and other diseases or disabilities with genetic components in their etiologies are included in the protection provided by the ADA, so long as these conditions either have consequences serious enough to limit substantially a major life activity or are regarded by others to produce substantial impairment of the person who manifests them. He also made a compelling argument that presymptomatic genetic conditions revealed by genetic testing should fall within the protective scope of the ADA, because (1) employers may perceive such presymptomatic conditions as impairments; and (2) case law interpreting the Rehabilitation Act of 1973

prevents employers from basing employment actions on projections of future disability.

Natowicz et al. (1992) suggest that presymptomatic genetic conditions are analogous to presymptomatic HIV infection and congenital back deformities that have been held to fall within the protection of the Rehabilitation Act of 1973 in cases that should constitute authoritative precedent for the ADA. As Holtzman and Rothstein (1992) have pointed out, however, the EEOC regulations implementing the ADA have rejected this interpretation, holding that presymptomatic individuals are not covered under the law.

State Regulation of Insurance Underwriting

As noted previously, federal law leaves regulation of insurance underwriting primarily to the states. All states have general statutes prohibiting life insurers from practicing "unfair discrimination" between individuals of the same risk class (i.e., equal expectation of life). Our survey of state insurance statutes indicated that all states except California prohibit health insurers from practicing unfair discrimination between individuals with essentially the same hazard.

Such statutes originally arose to prevent the widespread practice, among sales agents, of rebating (Wortham 1985). More recently, however, such statutes have been interpreted to prohibit both denial of coverage and premium differentials that are not supported by reasonable differences in risk (*Hilson v. Sun Life Assurance Co. of Canada,* 132 F.2d 989, 990 [5th Cir. 1943]); and *Reeves v. New York Life Insurance Co.,* 421 S.W.2d 686, 688 [Tex. Cir. App. 1967]). Persons denied coverage or charged a higher premium, either because of heterozygous carrier status or despite early detection and successful treatment of an expressed genetic condition, such as hemochromatosis (Billings et al. 1992), might challenge an insurer's adverse decision, on the basis of these general unfair-discrimination statutes. It is not clear, however, whether asymptomatic persons with a genotype associated with increased morbidity or mortality would be considered to have "equal expectation of life" or "essentially the same hazard" of disease or disability as do persons without such a genotype. Challenging, under general unfair-discrimination statutes, an insurer's adverse coverage or rating action based on genotype would probably require a court's finding of fact based on expert testimony. The great majority of states have neither legislation nor state insurance-office policy that makes this determination.

Several states have augmented their unfair-discrimination statutes, expressly to restrict the use of genetic information in underwriting. The majority of these statutes, however, narrowly limit protection—to genetic heterozygotes. Florida and Louisiana prevent life, health, and disability-income insurers from consideration of sickle-cell trait in determining eligibility or rates (Fla. Stat. §626.9706–07 [1990]; and LA. Rev. Stat. Ann. §22-652.1 [West 1991]). North Carolina and Tennessee prohibit consideration of sickle-cell or hemoglobin C traits in eligibility or rating decisions by life insurers, and North Carolina extends the same protection to health insurance as well (Gen. Stat. N.C. Ann. §§58-65-70, 58-51-45, 58-58-25 [Michie 1991]; and TN Code Ann §56-7-207 [Michie 1989]). California and Maryland prohibit life, health, and disability-income insurers from consideration of any nondeleterious heterozygous trait, but Maryland allows consideration of genetic traits for which there is actuarial justification (Ann. CA. Codes §10123.3 [West 1991]; and Ann. Code of MD. 484 §223 [Michie 1991]).

Other states do not limit protection to heterozygous traits. Alabama prohibits denial of health and disability coverage for applicants who have been diagnosed with sickle cell anemia (Code of Alabama §27-5-13 [Michie 1986]). Arizona and Montana protect persons with "any genetic condition" (defined as a specific chromosomal or single-gene condition) from discrimination in eligibility or rating differentials in life, health, or disability-income insurance, unless such determinations are supported by actuarial projections or claims experience (AZ, Reb. Stat. Ann. §20-448 [West 1990]; and Montana Code Ann. §33-18-206 [Montana Legis. Council 1991]). Recently, Wisconsin completely banned health insurers, as well as local government self-insurers of health benefits, from basing underwriting on the results of DNA tests. Life and disability-income insurers in Wisconsin, however, are allowed to use DNA test results, as long as these tests are "reasonably related to risk" (1991 Senate Bill 483 §1121q 631.89). The Pennsylvania legislature has considered a 2-year moratorium on insurance uses of genetic information, during which time the state health department would study the issue. The California legislature passed additional restrictions that were vetoed by the governor, but the issue is likely to be considered again in the next legislative session.

In sum, a review of extant federal and state regulation indicates relatively few restrictions on the use of genetic test results, by insurers or self-insured benefit plans, for risk assessment in insurance or health-care benefits. Arizona's and Montana's restrictions on genetic discrimination and Wisconsin's ban on the consideration of DNA tests in health insurance underwriting

constitute exceptions to this general lack of regulation. The remaining interest in such restrictions, in some state legislatures, indicates that restrictions are possible in the future. Public opposition to insurance-underwriting uses of genetic testing, which is reflected in public opinion polls, may reinforce legislative attention to the issue (Louis Harris & Associates 1985).

Conclusion

Our review of the way in which private insurance deals with personal medical information prompts an array of additional questions. These questions can be addressed not only by understanding how insurers and regulators have confronted new issues in the past but also by making reasonable inferences about the nature and impact of the genetic testing of the future.

1. *When should a new genetic test be used for health and for insurance risk prediction?* Recent experiences have suggested that pilot programs should be conducted prior to offering testing on a routine basis for health (Caskey et al. 1990; National Institutes of Health Workshop on Population Screening for the Cystic Fibrosis Gene 1990; Wilfond and Fost 1990; Dewar et al. 1991). These pilot programs allow for assessment of safety and efficacy, validity, and acceptance by the screened population; however, similar validation for hundreds of new tests may overtax current funding and testing mechanisms. Alternatively, the rationale for some new tests may be perceived as so compelling that they may find their way into medical practice, without extensive validation. Standards of accuracy, validity, and predictive value need to be developed not only for presymptomatic prediction and for confirmation of disease: similar standards should be developed for insurance underwriting.

2. *How will insurers use the information derived from genetic testing?* The advent of genetic screening for common diseases will present a new challenge for insurance-underwriting practices, because actuarial and claims experience will not be available for many years after these tests are introduced. Some projections are possible from the claims experience and morbidity and mortality of sporadic and familial cases of the diseases for which testing will be performed. Current underwriting practices for these diseases need to be analyzed and evaluated. Information for new conditions for which actuarial claims experience has not been generated frequently occurs in medical records. Analysis of how insurers currently handle these new conditions may provide insight into how they deal with genetic information derived from the medical record.

3. *Will insurers pay for genetic testing?* Insurance companies may have strong motivation to pay for testing, if presymptomatic detection of disease favorably alters claims experience. Information from genetic tests may help to reduce claims losses, by identifying and rejecting or surcharging individuals at high risk of loss. On the other hand, some insurance companies have favorable current experience with programs to alter life-style and improve health outcomes. This experience needs to be analyzed for its potential to be enhanced by the early intervention that will be made possible by genetic testing.

4. *Will genetic testing promote adverse selection?* Concerns about adverse selection should not be summarily dismissed (Report of the ACLI-HIAA Task Force on Genetic Testing 1991). Yet it is not clear how extensive these effects might be. Historical examples of adverse selection should be identified and carefully compared with the dramatic scenarios of market disruption that have been advanced. The underlying assumptions and dynamics of the effects of adverse selection must be analyzed carefully for each of the different forms of insurance.

5. *Are current legal and administrative practices sufficient to prevent genetic discrimination?* State and federal regulatory measures must be assessed for their sufficiency to assure fairness, confidentiality, and informed consent in the insurance applications, in regard to new genetic information. Some health-benefit mechanisms—for example, employer and union self-insurance benefits—remain relatively unregulated and exempt from state laws. It is yet undetermined whether the ADA will include within its protection presymptomatic individuals. The assessment should include sustained legal scrutiny of the EEOC's (1) exclusion, from the scope of the ADA protection, of presymptomatic persons and carriers of recessive and X-linked disorders (Juengst 1991) and (2) creation of a medical test confidentiality exception for insurers and employers that is not present in the ADA.

6. *How will public insurance mechanisms be affected by genetic testing?* As a consequence of genetic testing and possible exclusion from private insurance, the number of individuals in the public insurance pool may increase. Uninsured individuals who currently do not qualify for public insurance may then do so on the basis of genetic "hardship." Worse yet, some individuals excluded from private insurance coverage will not qualify for public insurance. Alternatively, preventive-health benefits and the possibility of acquiring insurance at standard rates may not be readily available to those

who cannot finance genetic testing either out of pocket or from Medicare or Medicaid. As with the current inequities of private health insurance, this may not constitute an efficient, rational, or fair policy.

The investigations outlined here will probably subject life, health, and disability-income insurance to considerable public scrutiny. Some parties will avoid dialogue and have already resisted the disclosure that could result from the public debate. Others will summarily dismiss legitimate concerns of consumers, insurers, and self-insuring employers. Resolution of these concerns will require open inquiry and a thorough analysis of all perspectives.

Acknowledgments

The authors thank the medical directors and underwriters of insurance companies, the representatives of the American Council of Life Insurance and of the Health Insurance Association of America, and the staff people in state insurance commissioners' offices and in state legislature insurance committees that made so much information available. The authors also thank Elizabeth Marks and Jeffrey Davis, M.D., M.P.H., for critically reading the manuscript and thank Linda Gentry, Debbie Sansone, and Cindy Pearson for their expert technical assistance. This work was supported in part by U.S. Public Health Service, National Institutes of Health, grant HG00402.

References

American Council of Life Insurance (1990) Life insurance fact book. Washington, DC

Beaudet AL, Scriver CR, Sly WAS, Valle D, Cooper DN, McKusick VA, Schmidke J (1988) Genetics and biochemistry of variant human phenotypes. In: Scriver CR, Beaudet AL, Sly WAS, Valle D (eds) The metabolic basis of inherited disease. McGraw-Hill, New York, pp 3–163

Beauregard K (1991) Persons denied private health insurance due to poor health. National Medical Expenditure Survey Data Summary 4. AHCPR pub 92-0016. Agency for Health Care Policy Research, U.S. Public Health Service, Rockville, MD

Billings PR, Kohn MA, de Cuevas M, Beckwith J, Alper JS, Natowicz MR (1992) Discrimination as a consequence of genetic testing. Am J Hum Genet 50:476–482

Caskey CT, Kaback MM, Beaudet AL (1990) The American Society of Human Genetics statement on cystic fibrosis screening. Am J Hum Genet 46:393

Congressional Research Service (1988) Health insurance and the uninsured: background data and analysis (reproduced in: Abraham K [1990] Insurance law and regulation. Foundation, Westbury, NY, pp 356–361)

Council on Ethical and Judicial Affairs, American Medical Association (1991) Use of genetic testing by employers. JAMA 266:1827–1830

Crandall LA, Moseley RE (1991) Public policy implications of scientific research: the human genome initiative and the future of insurance. New Biol 3:1135–1136

Dewar MA, Moseley R, Ostrer H, Crandall L, Nye D, Allen B (1991) Genetic screening and insurance carriers. JAMA 267:1208–1209

Friedman E (1991) The uninsured: from dilemma to crisis. JAMA 265:2491–2495

Gilbert SK (1986) The health insurance plight of patients with sickle cell disease. J Natl Med Assoc 78:663–685

Gostin L (1991) Genetic discrimination: the use of genetically based diagnostic and prognostic tests by employers and insurers. Am J Law Med 17:109–144

Harnett B, Lesnick I (1990) Law and life and health insurance, vol I. Matthew Bender, New York

Holahan J, Cohen J (1986) Medicaid: the trade off between cost containment and access to care. Urban Institute, Washington, DC

Holtzman NA (1989) Proceed with caution: predicting genetic risk in the recombinant DNA era. John Hopkins University Press, Baltimore

Holtzman NA, Rothstein MA (1992) Eugenics and genetic discrimination. Am J Hum Genet 50:457–459

Juengst E (1991) Priorities in professional ethics and social policy for human genetics. JAMA 266:1835–1836

Latrenta ND (1990) Privacy and fair information practices principles in the life insurance business. Paper presented at the Legal Section meeting of the American Council of Life Insurance, Houston, November 12–14

Lew EA, Gajewski J (1991) Medical risks: trends in mortality by age and time elapsed. Praeger, New York

Louis Harris & Associates (1985) Business Week/Harris poll: it's O.K. to 'play God'—within limits. Business Week (November 18), p 85

McKusick VA (1991) Genomic mapping and how it has progressed. Hosp Pract (Off Ed) 26:74–90

Medical Information Bureau annual report (1991) Medical Information Bureau, Westwood, MA

Mehr RI, Gustavson S (1987) Life insurance theory and practice, 4th ed. Business Publications, Plano, TX

Moseley RE, Crandall LA, Dewar MA, Nye D, Ostrer H (1991) Ethical implications of a complete human gene map for insurance. Business Professional Ethics J 10:69–82

National Institutes of Health Workshop on Population Screening for the Cystic Fibrosis Gene (1990) N Engl J Med 323:70

Natowicz MR, Alper JK, Alper JS (1992) Genetic discrimination and the law. Am J Hum Genet 50:465–475

Nelkin D, Tancredi L (1990) Dangerous diagnostics: the so-

cial power of biological information. Basic Books, New York

Pokorski RJ (1989) The potential role of genetic testing in risk classification. Report of the Genetic Testing Committee to the Medical Section of the American Council of Life Insurance, Hilton Head, SC, June 10

——— (1992) Use of genetic information by private insurers: genetic advances: the perspective of an insurance medical director. J Ins Med 24:60–68

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1983) Screening and counseling for genetic conditions. U.S. Government Printing Office, Washington, DC

Rejda G (1992) Principles of risk management and insurance, 4th ed. Harper Collins, New York

Report of the ACLI-HIAA Task Force on Genetic Testing (1991) American Council of Life Insurance and Health Insurance Association of America, Washington, DC

Sullivan CB, Rice T (1991) The health insurance picture in 1990. Health Affairs (Summer), pp 104–115

U.S. Congress Office of Technology Assessment (1988*a*) Mapping our genes—the genome project: how big, how fast? OTA-BA-373. U.S. Government Printing Office, Washington, DC

——— (1988*b*) Medical testing and health insurance. OTA-H-384. U.S. Government Printing Office, Washington, DC

——— (1992) Cystic fibrosis and DNA tests: implications of carrier screening. OTA-BA-532. U.S. Government Printing Office, Washington, DC

Vaughan E (1992) The fundamentals of risk and insurance. John Wiley, New York

Wilfond BS, Fost N (1990) The cystic fibrosis gene: medical and social implications for heterozygote detection. JAMA 263:2777–2783

Wortham L (1985) Insurance classification: too important to be left to the actuaries. J Law Reform 19:349–423