



AMERICAN ACADEMY *of* ACTUARIES

**Committee on Education and the Workforce
Subcommittee on Employer-Employee Relations
U.S. House of Representatives**

**Hearing on
Genetic Nondiscrimination:
Examining the Implications for Workers and Employers**

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**Statement of
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American Academy of Actuaries**

The American Academy of Actuaries is the public policy organization for actuaries practicing in all specialties within the United States. A major purpose of the Academy is to act as the public information organization for the profession. The Academy is non-partisan and assists the public policy process through the presentation of clear actuarial analysis. The Academy regularly prepares testimony for Congress, provides information to federal elected officials, comments on proposed federal regulations, and works closely with state officials on issues related to insurance. The Academy also develops and upholds actuarial standards of conduct, qualification and practice, and the Code of Professional Conduct for all actuaries practicing in the United States.

Chairman Johnson, Ranking Member Andrews, and distinguished committee members, I thank you for the opportunity to comment on an increasingly important issue that could have a significant impact on the health insurance market – the use of genetic information. My name is Tom Wildsmith, and I currently serve as the vice chairperson of the American Academy of Actuaries' Federal Health Issues Committee. I have also served as chairperson of the Academy's Task Force on Genetic Testing in Health Insurance. The Academy is the non-partisan public policy organization for actuaries of all specialties in the United States. I would like to submit for the written record the Academy monograph *Genetic Information and Medical Expense Insurance*, which expands on some of the key points that I will address today regarding genetic information and health insurance.

Legislation is pending before the House and has passed the Senate that would regulate the use of genetic information, particularly with respect to health insurance and employment. Scientific understanding of human genetics is advancing rapidly, but the technology continues to evolve. It is difficult to predict the impact this technology will ultimately have on the health insurance system. There are several key factors to consider in the public policy debate over the proper regulation of genetic information especially with respect to health insurance:

- Basing premiums and eligibility for coverage on a specific person's own health is a characteristic of the voluntary individual health insurance market – not the employer-sponsored group insurance market. Thus, while possible future use of genetic information for underwriting medical expense insurance is a potentially significant issue in the individual market, it is not a significant concern in the group market.
- Medical expense coverage is unique because, beyond the questions related to the use of genetic information, it involves the issue of whether the direct costs of genetic testing and treatment will be covered.
- Innovative disease management and prevention programs depend on the ability to identify patients and high-risk individuals for appropriate interventions. It is important that rules governing the use of genetic information not hamper the ability of such programs to improve care.
- All personal health information is, as it should be, protected – applying special rules to genetic information would increase the complexity of an already complicated health care system.

Policymakers must balance these and other competing social and economic concerns in considering legislation on this issue.

Group vs. Individual Medical Expense Insurance

Americans currently receive health care coverage through a variety of public and private systems. While some issues raised by genetic technology are common among most or all of these systems, others are specific to particular types of health care coverage. Information on the health status of individual program participants is not used to determine eligibility for participation in employer-sponsored health coverage – which covers nine out of 10 privately insured Americans.

Voluntary, individually purchased coverage in particular presents unique issues. A ban on the use of genetic information that would prohibit insurers from asking for genetic tests may remove applicants' fears of genetically based denial of coverage. However, barring insurers from obtaining test results already known to the applicant could result in adverse selection, which would have a direct impact on premium rates, ultimately raising the cost of insurance to everyone.

Any attempt to regulate the use of genetic tests and the information derived from them should provide a clear definition of the tests being regulated. If a ban on information obtained from "genetic tests" defines such tests broadly to include medical history or routine physical exams, it would severely hamper individual medical expense insurance underwriting, thereby increasing adverse selection.

Private group and individual health insurers do not currently require applicants for insurance to undergo genetic testing or use genetic testing to limit coverage for preexisting conditions. Of course, the current debate is really over the future. The various impact of genetic information on the health insurance system will change over time as the technology develops, and may often be overshadowed by broader societal concerns about the meaning and significance of genetic information. When balancing social and economic concerns, a clear understanding of the economic impact of alternative policies is vital.

Costs of Covering Genetic Testing and Treatment

The employer-sponsored medical expense insurance market will be faced with the question of whether the direct costs of various genetic technologies will be covered. It is unclear whether genetic technology will increase or decrease overall lifetime expenditures on medical care, and what the timing of those changes may be. We expect genetic tests that aid in the diagnosis of disease, and genetic treatments for disease, to be gradually recognized and covered by medical expense plans. Unless these new tests and treatments

produce an offsetting reduction in other medical expenses they may produce an overall increase in medical care costs.

Disease Management and Prevention

Employers are increasingly turning to a variety of targeted programs to prevent the development of disease in high-risk individuals, and to manage its progression in those who are already ill. To be successful, all of these programs depend on information. As we attempt to ensure that personal health information is not used against employees, it is important that we not inadvertently preclude its beneficial use on their behalf.

Confidentiality of Health Information

There is broad agreement that patients' privacy must be protected and the confidentiality of sensitive health information must be secured. The possibility of testing for abnormal genes has, in particular, raised fears about access to health coverage. However, underwriting and pricing for group insurance has historically focused on the overall makeup of the eligible group rather than the health of any particular individual – and HIPAA prohibits employers from using health status to deny coverage to an employee or to make them pay more than a coworker. (Of course, for small groups, a single high-cost individual can significantly affect the average cost of an entire group.) In addition, genetic information is subject to the same confidentiality rules as other forms of health information. While there may be particular sensitivities in the case of genetic information, this is part of the broader issue of health information confidentiality. Separate rules governing genetic information could increase complexity in an already complicated health care system.

Conclusion

For the employment-based health insurance system, the use of genetic information in individual underwriting is not a significant issue. As the technology advances and becomes a routine part of medical care, the question of how to pay for it will likely take on increasing significance. Personal health information is already subject to a variety of protections. Any additional protections placed on genetic information should allow for the use of such information in the development of new disease management and prevention programs, which could improve care and reduce costs. Rules governing genetic information should be balanced against the need to better manage an already complex health care system, and the need to use genetic information for legitimate, beneficial purposes. I would also note that the definitions in the first genetic information legislation to be enacted would likely set a precedent for the

future. As genetic science advances, it is inevitable that additional legislation will be needed to address future issues we cannot predict in advance. It is important that legislation in this area be drafted carefully, and reflect what is unique about the newly emerging genetic technologies.

Thank you for this opportunity to testify on behalf of the American Academy of Actuaries.

Public Policy Monograph

June 2000

Genetic Information
and Medical Expense
Insurance



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This monograph was prepared by the Academy Task Force on Genetic Testing in Health Insurance, which educates legislators and regulators about actuarial aspects of genetic testing, its use by health insurers, and related actuarial issues important to an understanding of the potential impact of genetic technology on the private health insurance system. The monograph's sole purpose is to assist the public policy process through the presentation of clear, objective analysis.

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Genetic Information and Medical Expense Insurance

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Genetic Information and Medical Expense Insurance

Executive Summary

Scientific understanding of human genetics is advancing rapidly, but the technology is not yet mature. It is difficult to predict the impact this technology ultimately will have on the insurance system. Key concerns that have been raised include access to health care, the cost of health care and health insurance, and the privacy of genetic information. Policy-makers must balance these and other competing social and economic concerns.

Key Issues

Americans currently receive health care coverage through a variety of public and private systems. Some issues raised by genetic technology are common among most or all of these systems; others are specific to particular types of health care coverage.

- The impact of genetic testing on the cost and delivery of health care likely will have an effect on all forms of health care financing.
- Genetic information is subject to the same confidentiality rules as are other forms of health information. While there may be particular sensitivities in the case of genetic information, this is a part of the broader issue of health information confidentiality.
- The possible future use of genetic information in risk selection and risk classification is a potentially significant issue only for the voluntary individual market.
- While most Americans are guaranteed access to some form of medical expense insurance, the cost of coverage varies significantly, and there are still some gaps. Filling those gaps could help reduce the potentially adverse impact of genetic testing on an individual's future ability to purchase medical expense insurance.

Costs of Covering Genetic Testing and Treatment

Any program of medical expense coverage will have to face the question of whether the direct costs of various genetic technologies will be covered. It is unclear whether genetic technology will increase or decrease overall lifetime expenditures on medical care, and what the timing of those changes may be. We expect genetic tests that aid in the diagnosis of disease, and genetic treatments for disease, to be gradually recognized and covered by medical expense plans as they are demonstrated to be more effective than other, more traditional approaches. Unless these new tests and treatments produce an offsetting reduction in other medical expenses, they may produce an overall increase in medical care costs.

Current Use of Genetic Technology

Information on the health status of individual program participants is not used to determine eligibility for participation in employer-sponsored medical expense programs — which cover nine out of ten privately insured Americans. Private health insurers do not currently require applicants for insurance to undergo genetic testing or use genetic testing to limit coverage for preexisting conditions. Insurers in the voluntary, individual medical expense market do ask applicants about their health and some may inquire about the results of any prior tests. Currently insurers rarely encounter any such infor-

Genetic Information and Medical Expense Insurance

mation. Once a medical expense insurance policy has been issued, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits cancellation based on the health of the policyholder.

Legislative Proposals and the Voluntary Individual Market

State and federal legislators have developed proposals to regulate the use of genetic information. While actuaries support many of these initiatives, proposals that ban the use of any genetic information may be overly broad, and conflict with the principles that underlie the financial soundness of voluntary, individually purchased medical expense insurance.

The process of risk classification is fundamental to a voluntary, individually purchased medical expense insurance market. Voluntary markets operate most efficiently where there is a rough equality of information between buyers and sellers. But individuals who know, or suspect, that they have genetic disorders fear that this information could be used to deny or terminate insurance coverage. When balancing social and economic concerns, a clear understanding of the economic impact of alternative policies is vital.

Some believe that banning the use of information gained from genetic testing in risk classification would help to alleviate problems in recruiting research subjects, would encourage individuals to seek out test results, and would reduce insurance fears. Unfortunately, such proposals often contain three elements that concern many actuaries:

- the scope of any definition of “genetic tests”
- any limitations placed on insurers’ knowledge of applicants’ health status that would result in asymmetric information
- the effect of new genetic testing technologies on the concept of preexisting conditions.

Definition of “genetic tests”: Any attempt to regulate the use of genetic tests and the information derived from them should provide a clear definition of the tests being regulated. If a ban on information obtained from “genetic tests” defines such tests to include medical history, routine physical examinations, and other routine laboratory testing, it would severely hamper individual medical expense insurance underwriting. Since some individuals’ health risks would be unknown, the pool of insurance purchasers might soon include a disproportionate number of people with higher-than-average anticipated medical expenses. This biased selection would cause premium rates to rise, making individual medical expense insurance even less affordable than it is now.

Asymmetric information: Would a ban on the use of genetic information merely prohibit insurers from asking for genetic tests, or would they also be barred from obtaining test results already known to the applicant? While a more encompassing ban may remove applicants’ fears of genetically based denial of coverage, the imbalance of information would leave insurers at a disadvantage. A ban on genetic information about minor conditions probably would not have a serious impact on insurers. In the case of more serious conditions, however, an information imbalance might allow one applicant to benefit financially over others by choosing the timing, type, and level of benefits purchased. This biased selection would have a direct impact on premium rates, ultimately raising the cost of insurance to everyone.

Preexisting Conditions: Preexisting conditions typically are covered on the same basis as any other condition, but only after an individual has been covered under a health plan for a specified period of

time (typically six to 12 months). However, state and federal laws increasingly limit the extent to which group and individual health plans may exclude coverage for preexisting conditions. Does a positive test result on a genetic test constitute a preexisting condition? Currently, for employer-sponsored health plans, HIPAA specifies that if genetic information is used to screen for a genetic predisposition to disease, and is not related to a diagnosis, it may not be treated as a preexisting condition. A similar approach might be appropriate for individually purchased medical expense insurance.

Guaranteeing all Americans access to medical expense insurance, while preserving the viability of a voluntary system of individually purchased insurance, is a difficult but important challenge that policy-makers have struggled with for a number of years. Some believe that banning the use of information gained from genetic testing in risk classification would alleviate problems in recruiting research subjects, would encourage individuals to seek out test results, and would reduce insurance fears. The impact of a ban on the use of genetic tests would depend on the ban's duration, the scope of the definition of "genetic testing" used, and the cost and predictive power of the tests covered by the ban. A moratorium on some types of tests would cause minimal disruption at first. However, such a ban could have more severe consequences over time, as genetic technology advances. A long-term ban on genetic testing has the potential to disrupt the voluntary individual medical expense insurance system, ultimately hurting the American people by making individual insurance more expensive and more difficult to obtain. On the other hand, mechanisms are needed to ensure that everyone has access to needed medical care.

Conclusion

The Academy believes that further research should be undertaken on the issues raised by genetic testing. Potential test recipients, physicians, plan sponsors, and insurers are all concerned by, and need information about, the implications of genetic test results for future health and health care expenses. Research focusing not only on survival rates and the probability of future disease, but on future health care needs and the availability, effectiveness, and potential cost savings of early intervention, is of great potential benefit. Not only would patients better understand their prognoses, but physicians could improve treatment modalities, and plan sponsors and insurers could better evaluate the appropriateness of covering specific tests, their likely impact on insurance costs, and their potential implications for risk classification in the individual market.

Some of the key questions that remain are:

- How accurately will genetic tests predict future health care needs?
- Will meaningful interventions be available for genetic disease?
- Will genetically based treatments become available?
- What impact will genetic technology have on overall medical care expenditures?

Policy-makers need a clear understanding of these issues so that proposals regulating the use of genetic testing information can find the best balance between the concerns of the public, the predictive ability of genetic test results, and the affordability of health insurance.

¹ Medicare Payment Advisory Commission, Report to the Congress-Selected Medicare Issues, June 1999

Introduction

Recent scientific advances in the understanding of human genetics, particularly those achieved by the Human Genome Project, hold the hope of significant progress in the prevention, diagnosis and treatment of disease. This in turn will affect the various public and private systems for financing medical care. It is difficult to predict what impact advances in genetic technology will have on the insurance system, because this technology is not yet mature¹. Interested groups are looking into a future that promises rapid and significant changes. Each group has unique concerns, and many are seeking legislative solutions to the problems they foresee. Key concerns include access to health care, the cost of health care and health insurance, and the privacy of genetic information. Policymakers must balance these and other competing social and economic concerns.

Americans currently receive health care coverage through a variety of public and private systems. While some issues raised by genetic technology are common among most or all of these systems, others are specific to particular types of health care coverage. Voluntary, individually purchased medical expense coverage in particular presents unique issues. Almost all elderly Americans are covered through the Medicare program. Most also have private coverage to supplement the benefits available through Medicare². Among the non-elderly, six out of ten are covered through employer-sponsored programs, and more than one out of ten are covered through public programs. While fewer than one out of ten are covered through individually purchased policies³, this market is an important residual source of coverage for those who do not have access to an employer-sponsored or government-sponsored program⁴.

The impact of genetic testing on the cost and delivery of health care will likely have an effect on all forms of health care financing. It is impossible to predict with confidence the future cost of covering genetic testing and genetic treatments, but that cost could potentially be significant. The possible future use of genetic information in risk selection and risk classification is, however, a potentially significant issue only for the voluntary individual market⁵. The various impacts of genetic technology on the medical expense insurance system will change over time as the technology develops, and may often be overshadowed by broader societal concerns about the meaning and significance of genetic information.

The American Academy of Actuaries is committed to assisting the political process by providing independent, non-partisan actuarial information on current public policy issues. This monograph on genetic information and medical expense insurance is provided for the information of elected officials, regulators, and the general public. It is based on the current state of genetic technology, and our understanding of potential future developments. Genetic technology is evolving rapidly, and its future course is difficult to predict with any certainty. Answers given today to questions raised by genetic technologies may no longer be valid tomorrow, and even the questions themselves may change over time.

¹Several alternative scenarios are outlined in the appendix. These are intended to illustrate a number of key factors that the work group believes will affect the future impact of genetic technology, and should not be interpreted as forecasts or predictions.

²EBRI Databook on Employee Benefits, Fourth Edition, Table 36.1, page 302, Employee Benefit Research Institute, 1997.

³Paul Fronstin, Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the 1997 Current Population Survey, EBRI Issue Brief Number 192, Employee Benefit Research Institute, December 1997

⁴Medicaid also serves as a residual source of coverage, serving "categorically eligible" low-income individuals.

⁵Risk Classification in Individually Purchased Voluntary Medical Expense Insurance, American Academy of Actuaries, January 1999. The market for very small employer groups is in many respects similar to the individual market, and similar considerations may apply.

Unless otherwise stated, the terms “genetic test” and “genetic testing” will be used to refer to tests whose immediate object is to determine the presence or absence of particular variations in a person’s genetic code, in contrast to tests whose immediate object is to examine the physical structure or functioning of a person’s body. Medical expense insurance is a form of health insurance. Other forms of health insurance include disability income insurance and long-term care insurance. This monograph focuses on medical expense insurance. The term “medical expense coverage” will be used on occasion to include self-insured employee benefit plans. The term “health insurance” will be used only when discussing concepts that apply to all forms of health insurance⁶.

⁶The term “health care coverage” is used by many as a synonym for medical expense coverage. This usage will be avoided in this brief to prevent confusion with the more general term “health insurance.”

Genes and Medical Expense Insurance

Background

The discovery of DNA has produced an explosion of research into the genetic structures fundamental to life and heredity. Since 1990, the Human Genome Project, a \$3 billion, 15-year joint effort of the National Institutes of Health and the U.S. Department of Energy, has been mapping the human genome. A complete map of the human genome could allow geneticists, researchers, and the medical profession to better understand and deal with human characteristics, including those that may lead to disease. Many have recognized that as we map the human genome and gain the ability to test individuals for gene abnormalities, we confront a host of ethical, legal, and social issues. A unique aspect of the Human Genome Project is that 3 percent to 5 percent of the annual budget for the project is allocated to studying the ethical, legal, and social issues surrounding availability of genetic information, making it the world's largest bioethics program.

For a number of years, newborns and their parents have been tested for several genetic birth defects, such as Tay-Sachs disease and Phenylketonuria. Fetuses are also routinely tested in utero to detect diseases such as Down's Syndrome. There are roughly two dozen genetic tests that can at this time be considered practical for adults (several dozen less practical ones are also available). While many more tests are expected to be developed during the next few years, currently only a few are clinically useful. Newer tests are generally being used to study specific populations and for experimental purposes. This is likely to be the case with any test until it can be incorporated into medical practice in a way that leads to meaningful medical decisions and advice to patients. Even so, advancing technology appears to be on the verge of creating genetic microchips that can screen for hundreds of genetic abnormalities at once⁷.

While there is a general perception that an individual who tests positive for a gene linked to a specific disease will contract that disease, in most cases a positive genetic test result indicates only an increased probability of developing such a disease. Only a few genetic abnormalities are known to lead directly and certainly to disease. The vast majority of genetic conditions require a combination of genetic and environmental factors in order to result in disease. Almost all of us are born with genetic risk factors, but it is not possible to determine when, or even if, individuals who are predisposed to a disease will actually contract it. Nonetheless, these genetic factors may provide an important indication of the relative health risks different individuals face.

Medicare, a social insurance program designed to cover medical expenses for Americans over age 65, does not consider an individual's health in determining eligibility or for establishing the premium paid by a beneficiary⁸. Because virtually all eligible individuals are covered, there is no concern that biased selection might increase overall program costs⁹. Private health insurers do not currently require

⁷Charles S. Jones, Jr. M.D., The Current State of Genetic Testing: An Insurance Industry Perspective on the Rush to Legislate, Thomas P. Bowles Symposium on Genetic Technology and Underwriting, March 26-27, 1998, Georgia State University, Atlanta, Georgia.

⁸The tendency for late enrollees to have higher than average medical costs, due to biased selection, is reflected in an increased Part B premium. Indicators of future claim levels (i.e., age, sex, institutional status and Medicaid eligibility) are used in establishing the capitation paid by the Medicare program to private Medicare+Choice plans for Medicare enrollees. A more accurate method of establishing Medicare+Choice plan payments is being developed.

⁹There have been suggestions, however, that biased selection by Medicare beneficiaries choosing between traditional fee-for-service benefits and HMO coverage may affect the overall cost of the Medicare program.

insurance applicants to undergo genetic testing, nor do they use genetic testing to limit coverage for preexisting conditions. Insurers in the voluntary, individual medical expense market do, however, ask applicants about their health and some may inquire about the results of any prior tests. Currently, insurers rarely encounter any such information¹⁰.

Fears About Insurability and Confidentiality

The possibility of testing for abnormal genes has, in particular, raised fears about access to medical expense coverage. Insured individuals who learn they carry genes linked to medical conditions worry their coverage may be canceled or their premium raised. Potential applicants for insurance fear they may be forced to take genetic tests, perhaps receive unwanted information about their health status, and perhaps be denied access to coverage now and in the future. Individuals are also concerned about the privacy of genetic information and the implications such information may have for their families and for their prospects for employment and career advancement. Researchers worry that fears about the use of genetic information will deter volunteers from participating in research projects. And finally, there is concern that insurers will use genetic tests to select only low-risk individuals, excluding many other individuals from coverage. These concerns lead some to believe that insurers should not be permitted to consider genetic test results in determining the cost and availability of insurance products.

Questions about Coverage and the Cost of Medical Care

The potential impact of genetic technologies on medical expense insurance goes beyond its effect on other forms of insurance. In addition to questions of access and privacy, any program of medical expense coverage must face the question of whether the direct costs of various genetic technologies will be covered. In addition, it is unclear whether genetic technology will increase or decrease overall lifetime expenditures on medical care, and what the timing of those changes may be. These are questions that will need to be continually reevaluated as genetic technology advances. In particular, since basic technical advances often have multiple applications and because advances in diagnosing or treating one disease often facilitate advances in dealing with other diseases, the number of genetic tests and treatments accepted into standard medical practice may grow quite rapidly once a critical level of base technology is achieved.

¹⁰Mark A. Hall and Stephen S. Rich, "Laws Restricting Insurers' Use of Genetic Information: Impact on Genetic Discrimination," *American Journal of Human Genetics*, January 2000.

Paul R. Lenz, M.D., F.A.C.P.E., The Current State of Genetic Testing in Health Insurance, Symposium Proceedings, Genetic Testing: Implications for Insurance, Sponsored by the MetLife Medical Department, the University of Pennsylvania Health System Center for Bioethics and The Actuarial Foundation, June 1997.

William J. Warfel, Ph.D., CLU, CPCU, Peter Mikolaj, Ph.D., Alex Hamwi, Ph.D., Genetic Information and Risk Classification in Individual Life and Health Insurance, *Journal of the American Society of CLU & ChFC*, September 1998. This Academy Task Force is not aware of any health insurer that requires applicants to take a genetic test.

Considerations Common to Both Employer-Sponsored Programs and Individually Purchased Insurance

Common Coverage Considerations

Genetic technology has a number of potential uses. One way of understanding these uses is by grouping specific genetic technologies into the following general categories: tests used for general population screening; tests used to screen populations at high risk for a particular disease; tests used in the diagnosis of disease; and treatments for disease¹¹. Each of these categories has implications for medical expense coverage.

Medical expense insurance has historically focused on covering the cost of medical care necessary for the diagnosis and treatment of an injury or an illness. This approach is consistent with the need to protect insured individuals from catastrophic medical costs, while avoiding coverage of expenses that are largely non-random or discretionary, because insurance is not generally an efficient way to fund such expenses. Over time, government-sponsored and employer-sponsored medical expense programs gradually began covering some preventive care and screening tests. This is at least partly because program subsidies, in the form of both sponsor contributions and tax preferences, have outweighed the economic inefficiency of using insurance to fund expenses that could otherwise be handled through routine budgeting. In addition, some forms of preventive care have been found by program sponsors to be cost-effective in reducing medical expenses that would otherwise be covered, and some programs of network-based managed care have been developed with a philosophical orientation toward coordinating all forms of "primary care."¹² Coverage of screening tests and preventive care is less prevalent in the voluntary, individual medical expense market, where program subsidies are generally limited or unavailable, and where the process of individual purchase decisions makes biased selection against the insurance system¹³ a more significant problem.

We expect genetic tests that aid in the diagnosis of disease, and genetic treatments for disease, to be gradually recognized and covered by medical expense plans as they are demonstrated to be more effective than other, more traditional approaches. From the standpoint of an insurance program, they are no different from any other new approach to diagnosis or treatment. Many new genetic tests have, at least initially, very high per-unit costs. The likely cost of future genetic treatments is not yet clear, but they may also have very high per-unit costs. Unless new tests and treatments produce an offsetting reduction in other medical expenses, or unit costs drop significantly, they may produce an overall increase in medical care costs.

Genetic screening tests for high-risk populations present a more complex question. If a high-risk population is relatively small and well defined, if a positive test result indicates a high likelihood of developing the disease, and if effective early interventions are available, then screening of that population may be cost effective¹⁴. If positive results do not strongly correlate with future disease, or if no

¹¹Others distinguish between diagnostic tests and predictive tests. We are characterizing predictive tests as screening tests, and distinguishing between those applied to the general population and those applied to specific high-risk populations because slightly different considerations may apply in the two cases.

¹²Non-specialist, basic medical care - typically, the care provided by a general practitioner or family physician, gynecologist or pediatrician, including routine physical examinations.

¹³Biased selection against an insurance program, also known as antiselection or adverse selection, occurs when applicants can expect to gain financially by making purchase decisions based on risk characteristics known or suspected by them but unknown to, or not considered by, the insurer or administrator of the program. The opportunity for biased selection arises from an imbalance in the information available to the consumer and the insurer.

¹⁴Because much genetic research has focused on specific ethnic and racial groups, genetic diseases for which tests have been developed are often closely associated with such groups. Because of this, even if well defined populations at risk can be defined, there may be social policy reasons for avoiding their use. This creates a difficult problem. If extended to the general population, a particular test may no longer be affordable. But, if it is limited to an ethnically or racially defined risk group, it may serve to reinforce negative stereotypes.

effective intervention is available, then the result of the screening test may have no direct impact on clinical care, and testing may not be medically appropriate. Of course, even if an effective intervention is available, high unit costs for either the test or the intervention itself may raise overall medical spending if not offset by other cost reductions. In addition, even if lifetime medical expenses are reduced, short-term medical expenses may increase. This could happen, for example, if screening and intervention early in life becomes practical for diseases of old age such as Alzheimer's disease. Costs would then rise for the programs providing medical expense coverage to non-elderly Americans, even though lifetime costs might ultimately fall, with Medicare benefiting from the reduction in the medical costs of old age. In the absence of legislative requirements, private medical expense plans are likely to decide whether to cover screening tests for high risk populations on the basis of their effectiveness relative to existing methods of screening and diagnosis, the cost effectiveness of early identification and intervention in reducing overall claim costs, and on consumer demand.

The use of genetic screening for large segments of the general population also requires tests that are highly predictive of future disease and have effective interventions, but in addition requires very low unit testing costs to be practical. Typically, most of the direct cost of a broadly based population-screening program will be for individuals who receive negative test results. In addition, if a test for a rare condition is used to screen the general population, a significant number of false positive results may be obtained, even if the test is highly accurate¹⁵. False negative results may be an even more serious concern because of their potential for providing a false sense of security, possibly leading to delays in treatment. Again, private plan sponsors are likely to make coverage decisions based on comparisons to existing medical practice, the cost effectiveness of screening in reducing future covered medical expenses, and on consumer demand.

Regardless of the populations involved, many screening tests will present plan sponsors with difficult ethical questions. For instance, by covering testing for BRCA mutations (which are correlated with an increased incidence of breast cancer), would a plan sponsor be encouraging women to take a test whose implications are not yet fully understood, and which may cause women to have radical, possibly unnecessary surgery? On the other hand, if a plan sponsor does not cover BRCA testing, is it failing to encourage the use of a procedure that has the potential to prevent breast cancer?¹⁶

Because prenatal screening tests pose particularly difficult ethical issues, it is difficult to predict the extent to which they will be covered. Tests for such diseases as Down's Syndrome are already being used to help parents decide whether to terminate a pregnancy. While many Americans have religious and moral objections to abortion, others are beginning to see this testing almost as a moral duty because of its potential impact on future generations. The availability of more tests is unlikely to reduce the controversy¹⁷.

¹⁵Even a very low error rate for a test, when applied to a large number of healthy individuals, may produce a large number of incorrect positive test results. If the condition involved is sufficiently rare, the number of false positive results may exceed the number of individuals correctly identified as having the condition. For a more complete discussion, please see Patrick L. Brockett, Richard MacMinn and Maureen Carter, Genetic Testing Insurance Economics and Societal Responsibility, Thomas P. Bowles Symposium on Genetic Technology and Underwriting, March 26-27, 1998, Georgia State University, Atlanta, Georgia.

¹⁶Current evidence indicates that prophylactic mastectomy may result in significant gains in life expectancy. Prophylactic oophorectomy (surgical removal of the ovaries) appears significantly less effective. For a discussion of the effectiveness of prophylactic surgery, see Deborah Schrag, MD, MPH, Cancer Prevention for Individuals with Inherited Mutations, Risk in Perspective, Harvard Center for Risk Analysis, Volume 6, Issue 5, May 1998 and Lynn C. Hartmann, MD, et al., Efficacy of Bilateral Prophylactic Mastectomy in Women with a Family History of Breast Cancer, New England Journal of Medicine, Volume 340, Number 2, January 14, 1999.

¹⁷Work is currently being done on in vitro fertilization, followed by pre-implantation genetic testing. It is unclear to what extent this might reduce ethical concerns about prenatal testing. This approach is also quite expensive.

Prenatal testing is likely to be viewed as particularly objectionable if it begins to deal with factors that might be considered eugenic, such as blindness, deafness, mild mental retardation, or susceptibility to heart disease or cancer. Some private-plan sponsors may have moral objections to paying for such tests, and there may be political objections to paying for them through publicly sponsored programs. Of course, the availability of appropriate and effective treatments would change the situation dramatically, but unfortunately testing technology appears to be advancing much more rapidly than treatment. Depending on its unit cost, prenatal treatment for serious genetic disorders might reduce the overall health care costs for pregnancies that are brought to term, while potentially raising them for pregnancies that would otherwise be terminated.

Tests that deal with susceptibility to disease, rather than the diagnosis of an illness that has already manifested itself, challenge our conventional ideas of what constitutes a medical condition or "disease," and when illness begins. The ability to test for genetic abnormalities that have not yet produced any symptoms will require plan sponsors to address how existing benefit provisions, such as pre-existing conditions clauses, should be applied to the new technologies.

Common Confidentiality Considerations

Genetic information presents serious confidentiality concerns, because of its very personal nature, public fears and uncertainty about its implications, and because an individual's genetic information may have potentially serious implications for family members. In addition to concerns about future access to health insurance, individuals contemplating undergoing genetic testing are often concerned that a positive test result could lead to social stigmatization or employment discrimination. While there may be particular sensitivities in the case of genetic information, this is a part of the broader issue of health information confidentiality.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a process for setting national standards for confidentiality of personal health information. In the event Congress did not enact national confidentiality standards by August of 1999, the Secretary of Health and Human Services was instructed to issue regulations establishing standards no later than August of 2000¹⁸. HIPAA also stipulates criminal penalties for wrongful disclosure of individually identifiable health information in violation of those standards. In September 1998, the National Association of Insurance Commissioners (NAIC) adopted a Health Information Privacy Model Act with a recommendation that it be enacted by state legislatures. If states enact this model, then it has the potential to strengthen and standardize the privacy protections already provided by state insurance law¹⁹. It is,

¹⁸As of early May 2000, no such legislation has yet been enacted, although several proposals are before Congress. Preliminary regulations have been exposed for comment, and the comment period has expired, but final regulations have not yet been issued.

¹⁹There are two relevant NAIC model acts. The first, the Insurance Information and Privacy Protection Model Act: 1) establishes standards for the collection, use and disclosure of information gathered in connection with insurance transactions by insurers and insurance related entities; 2) allows individuals the opportunity to access and verify the accuracy of information maintained about them by these entities; and 3) enables applicants for insurance to obtain the reasons for any adverse underwriting decision. This model act has been adopted by seventeen states (AZ, CA, CT, GA, HI, IL, KS, ME, MA, MN, MT, NV, NJ, NC, OH, OR, & VA).

The second is the more recent Health Information Privacy Model Act, which imposes much more detailed and prescriptive mandates on health plan operations and procedures. No states have adopted this model to date.

While not all states have adopted one of the NAIC models on this issue, almost every state has one or more laws that directly or indirectly relate to how insurers must protect the confidentiality of personally identifiable health or insurance information.

however, unclear whether the federal standards, when ultimately established, will preempt existing state standards.

Some policy-makers and consumers are particularly concerned that health insurers will not maintain the confidentiality of genetic test results revealed on applications for insurance. However, disclosure of personal health information is not required for enrollment in employer sponsored medical expense programs²⁰. Even in the case of voluntary, individually purchased medical expense insurance, state law requires insurers to keep all underwriting information confidential. Currently, an applicant's consent is required before an insurer is permitted access to personal medical records. The confidentiality of this information is protected by law, and its use by insurers is tightly restricted. In the 1980s and early '90s, many states reviewed and strengthened their confidentiality laws in response to the AIDS epidemic, and the continuing regulatory trend is to toughen such safeguards.

²⁰HIPAA prohibits employer-sponsored group health plans from basing enrollment eligibility on health status, medical condition, claims experience, receipt of health care, medical history, genetic information, evidence of insurability or disability. No plan participant may be required, on the basis of any health status related factor, to pay a higher premium or contribution than that of a similarly situated participant. ERISA Title I, Subtitle B, Part 7, Section 706 as amended by HIPAA Title I, Subtitle A, Part 1, Section 101. State insurance law governs the premiums that a health plan charges an employer for insured coverage.

Employer-sponsored Medical Expense Programs

Access and Renewability

Employer-sponsored medical expense plans are generally structured with a significant subsidy from the employer, ensuring that participation is attractive to the healthy as well as to those who anticipate significant medical expenses. Because of this, these group plans are less likely to experience a disproportionate enrollment of relatively unhealthy individuals than are individually purchased medical expense insurance policies. Historically, underwriting and pricing for group insurance has focused on the overall makeup of the eligible group rather than the health of any particular individual²¹. HIPAA now prohibits “group health plans”²² from basing eligibility on the health of an individual²³. Genetic information is explicitly included in this prohibition. Any insurer offering medical expense insurance in a state is required to accept any small employer from that state who applies for coverage²⁵. According to the U.S. General Accounting Office “[v]irtually all medium and large employers have access to group health insurance, and about 90 percent actually offer health coverage to their employees.”²⁶ HIPAA also requires guaranteed renewability of coverage for both small and large employers.²⁷

Enrollee Self-Selection and Costs

In most cases, employer-sponsored plans should not be seriously affected by a disproportionate number of high-cost individuals enrolling as a result of genetic information. Among the very smallest employer groups, those with an owner or key employee with poor health or high anticipated medical

²¹Risk Classification in Individually Purchased Voluntary Medical Expense Insurance, American Academy of Actuaries, January 1999.

²²Defined as employee welfare benefit plans, as defined by the Employee Retirement Income Security Act of 1974 (ERISA), that directly, through insurance, or otherwise provide benefits or reimbursement for medical care. Accident and disability insurance, liability insurance or coverage supplemental to liability insurance, worker's compensation insurance, automobile medical payment insurance, credit insurance, coverage for on-site medical clinics, and other similar secondary or incidental benefits as specified by regulation are excluded. Limited scope dental or vision benefits, long-term care, nursing home, or home-health care, and other similar, limited scope benefits are excluded if offered separately. Specified disease and hospital or other fixed indemnity coverages are also excluded if offered as independent, noncoordinated benefits. Medicare supplement benefits are also excluded if offered as a separate insurance policy. ERISA Title I, Subtitle B, Part 7, Section 706 as amended by HIPAA Title I, Subtitle A, Part 1, Section 101.

²³ERISA Title I, Subtitle B, Part 7, Section 702 as amended by HIPAA Title I, Subtitle A, Part 1, Section 101.

²⁴Small employers are defined as those with at least two, but no more than 50, employees. Public Health Service Act, Title XXVII, Part C, Section 2791(e)(4) as amended by HIPAA Title I, Subtitle A, Part 1, Section 102.

²⁵Public Health Service Act, Title XXVII, Part A, Subpart 2, Section 2711 as amended by HIPAA Title I, Subtitle A, Part 1, Section 102. Provision is made for limitations in managed care network service areas, the capacity of networks to provide medical services, and the reserve capacity of insurers.

²⁶Larger firms are more likely to offer coverage than are smaller ones, and full-time employees are more likely to be eligible to participate than are part-time or temporary employees. Employment Based Health Insurance: Medium and Large Employers Can Purchase Coverage, but Some Workers Are Not Eligible, United States General Accounting Office, GAO/HEHS-98-184, July 1998

²⁷Exceptions are made for nonpayment of premiums, fraud, violation of participation or contribution rules, movement outside of a plan's service area, or in the case of coverage offered through a bona-fide association the termination of association membership. Provision is also made for insurers to update their products on a uniform basis, and to withdraw from the market in a particular state. Public Health Service Act, Title XXVII, Part A, Subpart 2, Section 2712 as amended by HIPAA Title I, Subtitle A, Part 1, Section 102.

costs may be somewhat more likely to seek coverage. If covered genetic therapies have very high unit costs, they may significantly impact the cost of smaller plans that happen to have an individual needing treatment. This would be similar to the way in which a transplant case or premature infant can significantly raise a small plan's costs for a given year. It is also possible that the widespread availability of genetic testing or treatment will raise the overall level of claim expenditures and, in turn, premiums for employer-sponsored programs. Because employer-sponsored plans are tax-subsidized fringe benefits as well as insurance programs, they are probably more likely to cover screening tests and preventive care than are individually purchased policies.

Individually Purchased Medical Expense Insurance

Access

Many states give insurers flexibility in establishing initial premiums for individual medical expense insurance, and most states give insurers a great deal of flexibility in accepting or rejecting each application for coverage. Because most consumers only keep their policies in force for a few years, the underwriting of medical expense policies focuses on medical care costs likely during the first few years after a policy is sold²⁸. Family history is rarely, if ever, used in evaluating applicants for individual medical expense insurance because it has not proven to be a good predictor of short-term medical costs. It seems likely that most genetic screening tests will identify the same types of hereditary susceptibilities to disease that might otherwise be revealed by family history. Because of this, we do not anticipate that most individual medical expense insurers will, in the foreseeable future, routinely require predictive genetic screening tests of applicants, even if allowed to do so. On the other hand, individuals who have undergone genetic testing for other reasons and thus have personal knowledge of a specific genetic susceptibility or disorder may be more likely to purchase coverage. Because of the adverse impact that this self-selection could have on their expected costs, individual market insurers do ask for the results of any prior genetic testing²⁹.

Where genetic information is available, it will not have a uniform effect on availability of voluntary, individual medical expense insurance. Some people could benefit from greater access to coverage; others with specific genetic conditions could see reduced access to coverage or higher premium costs. In some cases genetic information will lead to early treatment or rule out a particular predisposition to disease. In other cases it may confirm the likelihood of future illness. Depending on the predictive power of the test, the seriousness of the disease, the likely timing of its manifestation, and the cost of treatment, this information may or may not prevent the individual from being able to purchase individual medical expense insurance at a standard premium.

If information about a disease were to prevent an individual from participating in the voluntary, individual medical expense insurance market, other sources of coverage might currently be available. Most recent efforts to restructure or reform the individual medical expense insurance market have focused on guaranteeing access to coverage for those who would otherwise be considered medically uninsurable³⁰. COBRA continuation coverage provides significant short-term protection to individuals leaving employers with 20 or more employees. HIPAA guarantees access to coverage to certain individuals who lose group medical expense coverage³¹, but at a cost that varies significantly from state to state³². Currently, 13 states have a guaranteed-issue requirement in the individual medical expense

²⁸Disability income and long-term care policies, in contrast, are typically viewed by buyers as permanent insurance. As a result, the underwriting of those products considers the long-term health of applicants.

²⁹For a more complete discussion of the use of medical underwriting in the individual medical expense insurance market, please see the Academy issue paper Risk Classification in Individually Purchased Voluntary Medical Expense Insurance, American Academy of Actuaries, January 1999.

³⁰For a more complete discussion of the actuarial issues surrounding guaranteed access, please see the Academy monograph Providing Universal Access in a Voluntary Market, American Academy of Actuaries, February 1996.

³¹Public Health Service Act, Title XXVII, Part B, Section 2741 as amended by HIPAA Title I, Subtitle B, Section 111. Their most recent prior coverage must have been with a group health plan, governmental plan or church plan; they must be ineligible for group medical expense coverage, Medicare Parts A or B, Medicaid, and without any other medical expense coverage; they must not have been terminated from their most recent prior coverage for nonpayment of premiums or fraud; they must have exhausted any COBRA coverage available to them; and they must have had at least 18 months of "prior creditable coverage." Most forms of medical expense coverage count as creditable coverage, as long as it has not been interrupted by a break in coverage of more than 63 days (COBRA coverage also counts toward the 18-month requirement). The mechanism used to provide access varies by state.

³²Concerns have been expressed that some HIPAA-eligible individuals may encounter access barriers and high premiums in the 13 states that have implemented the default "federal fallback" rules. These default rules require the guaranteed issue of individual

insurance market, requiring insurers to issue some form of coverage to all applicants regardless of health status (specifics, such as the type of policy that must be issued, vary by state), and 20 states limit the extent to which insurers can vary premium rates between individuals or the risk characteristics they may consider³³. High-risk health insurance pools have been created in 27 states to ensure access to individuals who would otherwise be medically uninsurable³⁴. In other states, Blue Cross and Blue Shield plans guarantee access during annual open enrollment periods³⁵. Six states³⁶ have no mechanism in place to guarantee access to uninsurable individuals who are not eligible for HIPAA-mandated coverage³⁷.

Renewability

Contract provisions and state insurance law restrict a health insurer's ability to raise an individual's premium once the policy is in force, and have historically restricted an insurer's ability to cancel a policy. Typically, the insurer can only raise premiums if the increase is applied uniformly to a "class" of policyholders, usually defined as all policies of a particular type sold in a given state. Most states reserve the right to review and disapprove rate increases. HIPAA prohibits the cancellation of a medical expense policy based on the health of the policyholder.

Costs and Coverage

Depending on unit costs, and the offsetting savings from more traditional services that would otherwise be required, the widespread availability of genetic diagnostic testing or treatment has the potential to raise the overall level of claim expenditures, and, in turn, premiums, for individually purchased medical expense insurance policies. Even though these policies are more likely to be affected by beneficiary self-selection than are employer-sponsored programs, individually purchased policies are probably less likely to face increased expenses due to the direct cost of screening tests. Because individuals purchase these policies directly and face the full cost of the premiums with limited, if any, tax subsidy, they typically select less expansive coverage than is provided by employer-sponsored plans. As a result, individually purchased medical expense policies are probably less likely to cover screening tests and preventive care than are employer-sponsored plans.

health insurance policies to HIPAA-eligible individuals, but do not limit the premiums that may be charged. It appears that most states implementing an alternative mechanism are including a requirement for risk spreading, some form of premium regulation, or an explicit subsidy. Letter from William J. Scanlon, Director, Health Financing and Systems Issues, U.S. General Accounting Office, to the Honorable Nancy L. Johnson, Chairman, Subcommittee on Oversight, Committee on Ways and Means, House of Representatives, "Alternative Mechanisms" Under HIPAA, GAO/HEHS-98-161R, May 20, 1998.

³³Private Health Insurance: Declining Employer Coverage May Affect Access for 55- to 64-Year-Olds, GAO/HEHS-98-133, U.S. General Accounting Office, June 1998, page 80.

³⁴Ibid., page 81.

³⁵Ibid., page 81.

³⁶Alabama, Arizona, Delaware, Georgia, Hawaii and Nevada. Hawaii mandates employer-sponsored health insurance. As a result, relatively few Hawaiians must rely on the individual health insurance market for coverage.

³⁷Private Health Insurance: Declining Employer Coverage May Affect Access for 55- to 64-Year-Olds, GAO/HEHS-98-133, U.S. General Accounting Office, June 1998, page 82.

³⁸Exceptions are made for nonpayment of premiums, fraud, movement outside a plan's service area or, in the case of coverage offered through a bona-fide association the termination of association membership. Provision is also made for insurers to update their products on a uniform basis, and to withdraw from the market in a particular state. Public Health Service Act, Title XXVII, Part B, Section 2742 as amended by HIPAA Title I, Subtitle B, Section 111.

Key Questions

How accurately will genetic tests predict future health care needs?

Some believe that genetic technology will eventually be able to chart accurately an individual's medical future, and are concerned about the ways in which that ability might be used. While tests for some single-gene disorders may prove almost certain predictors of disease, in most cases illness is likely to arise from a complex interplay of many genetic, environmental, and lifestyle factors, and testing will reveal predisposition rather than fate. For instance, an individual with a genetic predisposition for diabetes may, through a program of weight control, reduce the probability of developing the disease. While the predictive value of genetic testing will likely improve over time, currently it is limited.

Will meaningful interventions be available for genetic disease?

Some are available now. For example, individuals who suffer from hemochromatosis, or iron-rich blood, face serious medical consequences if their condition is left undetected and untreated. However, if a test reveals genetic predisposition for the condition, early treatment, which usually is low in cost, can prevent complications and avoid early death due to the condition. There is evidence that prophylactic surgery may be an effective intervention for women with the BRCA1 and BRCA2 genes. If, as genetic technology advances, we are able to identify predispositions for conditions such as obesity, diabetes, or coronary artery disease, lifestyle interventions may prove useful. For other conditions there may be no useful intervention. The availability of effective treatment, along with the predictive power of a test, will largely determine its practical value. If the results of a test do not lead to a change in clinical treatment, the test will most likely not be considered medically necessary and as a result not be covered by most medical expense programs.

Will genetically based treatments become available?

Genetic treatment appears to be developing more slowly than genetic testing. However, once a genetic mutation has been identified, it seems natural to ask whether it can be repaired, or if the product of the affected gene can be artificially replaced. Such treatment would hold the potential to significantly improve the health of affected individuals. Depending on the unit cost of treatment, whether it was a one-time repair or an on-going maintenance program, and on the cost of other care that would be avoided, it could either reduce lifetime health care costs or significantly raise them.

Genetic technology also may allow the growing of replacement tissues and organs tailored for specific individuals. The use of transplant technology is currently limited by the availability of donor organs, and by the need to deal with donor/recipient compatibility and tissue rejection. If genetically engineered replacement tissues and organs become available, the frequency of transplantation may increase dramatically. Two other factors affecting the impact of genetic technology on lifetime health care costs will be the expense of genetically engineered tissues and organs relative to the expense of donor tissues and organs, and the extent to which a reduced risk of tissue rejection reduces the need for follow-up care and repeat transplants.

What impact will genetic technology have on overall medical care expenditures?

The impact of genetic technologies on overall medical care expenditures will depend on the unit costs of the technologies, how often their use is required, and what offset savings are created by reductions in the use of other more traditional services that may no longer be needed. It is impossible to predict the impact that developing technologies will have. Historically, however, most advances in medical technology have increased total expenditures, rather than reduced them. While genetic technology holds the promise of improved health, that improvement may come at an economic price.

Current Concerns

Access to Medical Expense Insurance

Genetic disease, like any other health factor, may not be used to restrict eligibility for participation in employer-sponsored health plans.³⁹ Insurers in the individual medical expense market do not require genetic testing of applicants, but in most states are allowed to inquire about the results of any previous tests. Most individuals in most states have guaranteed access to medical expense insurance, though the nature of the program and its costs may vary significantly.⁴⁰ The exceptions are non-HIPAA eligible individuals in the six states that have not implemented any mechanism for guaranteed access to medical expense insurance for those individuals. Once a person has purchased medical expense insurance there are a limited number of reasons for which it may be canceled, none of which has anything to do with the person's health.

Potential Difficulties in Recruiting Participants for Genetic Research Studies

Researchers are currently reporting some difficulty in recruiting research study participants. This is a result of the informed-consent process and fears about the use of information and resulting discrimination. A primary fear is that future access to medical expense coverage may be compromised.

As described above, access to employer-sponsored medical expense programs cannot be denied based on genetic information, or indeed on any other health factor. Both group and individual medical expense coverage already in force cannot be canceled due to genetic information or health status, nor can an individual be singled out for a rate increase. Individuals may, of course, lose their eligibility for employer-sponsored coverage due to a change in employment, or for other reasons. Federal law, under COBRA and HIPAA, guarantees continuing access to coverage for those losing employment-based coverage.⁴¹ Particular concerns have been expressed about access and affordability in the 13 states that have not implemented an "alternative mechanism" for providing HIPAA-mandated access, but have instead relied upon the default "federal fallback" rules.⁴² Implementation of a high-risk pool or other mechanism to subsidize coverage for HIPAA-eligible individuals in those states could help address those concerns.

Some people may not have access to an employer-sponsored program. In most states some form of guaranteed access to coverage is provided, even for individuals who do not qualify for guaranteed access under HIPAA. Of course, the details of the program and the costs involved vary significantly by state, and there are currently six states that do not have any form of guaranteed access for individuals who are not qualified under HIPAA. Providing guaranteed access to health insurance to all individuals in those states through high-risk pools or other mechanisms could help reduce the need for concern. In any event, participation in a blind study that does not inform participants about their test results would have no effect on insurability.

³⁹ As noted above, HIPAA prohibits employer-sponsored plans from using health status, including genetic information, as a basis for eligibility.

⁴⁰ As discussed earlier, thirteen states have enacted individual market guaranteed-issue requirements, twenty-seven states have established high-risk health insurance pools, and in others guaranteed access is provided to Blue Cross and Blue Shield plans during annual open enrollment periods.

⁴¹ Premiums for COBRA continuation coverage are limited to 102 percent of the average cost to the employer-sponsored plan for active employees and their dependents. The mechanism through which HIPAA coverage is provided, and the cost to purchasers, vary significantly by state.

⁴² Health Insurance Standards: New Federal Law Creates Challenges for Consumers, Insurers, Regulators, U.S. General Accounting Office, GAO/HEHS-98-67, February 1998

Potential research participants also fear social stigmatization and employment discrimination if a positive test result becomes known. They often fear that, in order to avoid potentially high benefit costs and the costs of recruiting and training replacement workers, employers may be less likely to hire or retain individuals with a genetic predisposition to disease. The Americans with Disabilities Act (ADA), state disability discrimination laws, existing state privacy laws and the model act on health information privacy recently adopted by the NAIC and recommended to the states for enactment, are intended to address these concerns for all types of health conditions, and not just genetically based conditions.

Legislative and Regulatory Issues

In response to growing public concern, legislators at both the state and federal levels have developed proposals to regulate the use of genetic information. Many of these initiatives reinforce well-established industry practices concerning confidentiality and disclosure of sensitive information. Actuaries fully support many of these initiatives. However, some legislative initiatives would go so far as to ban use of any genetic information. Such limitations conflict with the principles that actuaries believe underlie the financial soundness of voluntary, individually purchased medical expense insurance and consequently have raised concerns among many actuaries. Voluntary markets operate most efficiently where there is a rough equality of information among buyers and sellers. When balancing social and economic concerns, a clear understanding of the economic impact of alternative policies is vital.

It has been suggested that banning the use of information gained from genetic testing in risk classification would alleviate problems in recruiting research subjects, encourage individuals to seek out test results, and reduce insurance fears. Unfortunately, such proposals often contain two elements that are of serious concern to many actuaries: the definition of “genetic test” and limitations on insurer knowledge of applicants’ health status that would result in “asymmetric information.” A related issue is how the new genetic testing technologies affect the concept of “preexisting conditions.”

Definition of “genetic tests.”

Most people assume that the term “genetic testing” is reasonably well defined. Actually, the range of procedures that are sometimes considered genetic tests is broader than is commonly assumed.

DNA-based tests that tie specific conditions to specific genes are becoming more common as research advances through the work of the Human Genome Project. These tests are commonly cited in the debate about genetic privacy in underwriting. However, genetic information also is revealed through tests that insurers have used for many years. For example, blood and urine tests reveal evidence of conditions that may have a genetic basis, and which insurers take into account in their risk classification procedures as a matter of course. Should such analyses be considered tests for genetic information similar to DNA-based tests? Any attempt to regulate use of genetic tests and the information derived from them should provide a clear definition of the tests being regulated.

In the event of regulatory restrictions, the scope of such a definition of genetic testing would have a serious impact on insurers and consumers. A total ban or moratorium on information obtained from genetic tests – if broadly defined to include medical history, routine physical examinations, or routine laboratory testing of the structure and function of the body – would severely hamper individual medical expense insurance underwriting.

An analogy might be to fire insurance. Imagine that there were good reasons to prohibit fire insurers from going to the building department and pulling the blueprints on structures that they were considering insuring. This might not be a serious impediment if they were still allowed to send in building inspectors to examine the physical structures involved. However, fire insurance might well become impractical if insurers were required to cover buildings sight unseen. In a sense, genetic technology is giving us, for the first time, access to human “blueprints.” Not being able to directly access the blueprints (i.e., require applicants to undergo genetic testing) may not adversely affect the individual medical expense market as long as insurers are still able to examine physical structure and functioning (i.e., through medical history, routine examinations and laboratory tests). Of course, if the applicant has voluntarily undergone genetic testing in the past, that information may be relevant also.

Under a broad ban that includes information from routine physical examinations, some individuals’ health risk would be unknown and hence the pool of insurance purchasers might soon include a disproportionate number of individuals with higher-than-average anticipated medical expenses. This

biased selection would cause premium rates to rise, making individual medical expense insurance even less affordable than it is now.

Asymmetric information.

Would a ban on the use of genetic information in individual medical expense insurance underwriting merely prohibit insurers from asking for tests to be performed or would they also be barred from obtaining test results the applicant already knows? Clearly, a more encompassing ban would more completely remove applicant fears of genetic-based denial of coverage. However, from an insurer's point of view, there is a world of difference between the two prohibitions.

When purchasing insurance, consumers weigh the price they must pay against the value they expect to receive. Individuals generally will not pay significantly more in premiums than they expect to receive back in benefits. Most healthy individuals are willing to pay a premium somewhat higher than the benefits they would receive given their usual health care expenditures, in order to have the peace of mind provided by protection against unanticipated injury or illness. However, there is a limit to the additional premium any given consumer is willing to pay in order to obtain this peace of mind. If premiums for a health insurance policy rise above this threshold, then healthy individuals will not purchase the coverage. If no insurer offers coverage at a premium below this threshold, healthy individuals will drop out of the insurance marketplace.

Whenever an applicant knows critical information but the insurer does not, the asymmetry of information may lead to biased selection, depending on the value of the information for predicting future health care needs and thus the potential impact on premium costs. This could result in insurance becoming less affordable. As prices rise, consumer buying patterns may change. With healthier individuals becoming less likely to purchase coverage, average claims costs would increase, and prices would rise yet again to keep the system in balance. These increasing prices would not only affect affordability, but over the long term could also cause insurers to withdraw from the market or restrict coverage.

Some have suggested that individuals would be more likely to use helpful genetic information if individual medical expense insurers were prohibited from using genetic information already known to applicants. Certainly, putting information about minor conditions that do not indicate a significant increase in future health care needs "off limits" would not have a serious impact on the insurer. However, in the case of a medical condition with more serious consequences, an information imbalance might allow the applicant to financially benefit, relative to other purchasers, by choosing the timing of purchase, and the type and level of benefits purchased. This biased selection would have a direct impact on premium rates, ultimately raising the cost of insurance to everyone.

The impact of a ban on insurance company use of genetic tests would depend on the ban's duration and the scope of the definition used. A moratorium on some types of tests would cause minimal disruption at first, but could have more severe consequences over time. This is primarily because the new genetic tests of DNA are currently very expensive and provide little additional information about the probable health care needs of an individual. When tests become more accurate, less expensive, and better able to detect a wide range of conditions, this is likely to change.

Preexisting Conditions.

Historically, medical expense policies have either excluded or limited coverage for expenses incurred as a result of medical conditions that existed or became obvious to the covered individual before

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becoming insured. This is intended to prevent individuals from seeking coverage only when they need medical care, and discontinuing coverage during periods of good health.

Employer-sponsored programs typically exclude or limit benefits for an injury or illness that occurred during a specified period, such as three or six months, prior to the effective date of coverage. Preexisting conditions are typically covered on the same basis as any other condition after an individual has been covered under the plan for a specified period of time (typically six to 12 months). Individual medical expense policies generally exclude coverage for preexisting conditions for a specified period of time, typically either one or two years.⁴³ However, state and federal laws are increasingly limiting the extent to which group and individual health plans may exclude coverage for preexisting conditions.⁴⁴

As genetic tests become increasingly available, the question of whether or not a positive test result constitutes a preexisting condition will arise. An important consideration may be whether a given test is used to screen for a genetic predisposition to disease, or is used diagnostically to identify or confirm the existence of a particular condition. For employer-sponsored health plans, HIPAA uses this distinction to specify how genetic information may be used for purposes of applying preexisting condition limitations, explicitly stating that if genetic information is not related to a diagnosis, it may not be treated as a preexisting condition.⁴⁵ A similar approach might be appropriate for individually purchased medical expense insurance.

⁴³ Preexisting condition limitations apply to medical conditions that already exist at the time application is made for coverage, even if the insurer is not aware of them. Contract riders may be used to limit or exclude coverage for conditions that become evident through the application or underwriting process.

⁴⁴ Many states restrict the applicability of preexisting conditions limitations for both small group and individual coverage, by limiting the period of time during which coverage for preexisting conditions may be excluded or by requiring carriers to credit prior health coverage against the preexisting conditions exclusion period. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) has a number of provisions to minimize the impact of preexisting conditions limitations on insured individuals. With group health plan coverage an exclusion of up to 12 months can be imposed only once, the "look-back" period cannot exceed six months, and when insured individuals change plans the new plan must give credit for previous coverage toward any new preexisting condition limitation. Qualified individuals losing group health plan coverage must be provided access to individually purchased coverage, although the mechanism used varies from state to state, and must be given credit for prior coverage against any new preexisting condition limitation. ERISA Title I, Subtitle B, Part 7, Section 701 as amended by HIPAA Title I, Subtitle A, Part 1, Section 101; Public Health Service Act, Title XXVII, Part A, Subpart 1, Section 2701 as amended by HIPAA Title I, Subtitle A, Part 1, Section 102; Public Health Service Act, Title XXVII, Part B, Section 2741 as amended by HIPAA Title I, Subtitle B, Section 111.

⁴⁵ ERISA Title I, Subtitle B, Part 7, Section 701 as amended by HIPAA Title I, Subtitle A, Part 1, Section 101.

Coverage Options

In evaluating the concerns raised by genetic information, it is important to understand the sources of coverage already in place. There are a number of alternative sources of health insurance coverage currently available. Six out of 10 Americans are covered through employment-based plans, and one out of four are covered through government-sponsored plans.⁴⁶ Most individuals already have guaranteed access to health insurance, although for some individuals who are not eligible for employment-based coverage the cost may be high. The coverage needs of participants in genetic research projects may require special consideration.

Options Currently Available

- Coverage through employer-sponsored programs.
- Individually purchased voluntary medical expense insurance for those who qualify.
- Guaranteed-issue COBRA or HIPAA coverage for those who qualify.
- Guaranteed-issue coverage through high-risk pools or other state programs for the medically uninsurable.
- For some, individually purchased coverage with an extra premium reflecting the added risk.
- For specific population segments, government programs such as Medicare and Medicaid.

Potential Options for Research Participants

- Increased use of blind studies to avoid any impact on future insurability.
- Requirement of existing coverage for study participation.
- Purchase of catastrophic coverage on a group basis for all study participants.
- Purchase of specified disease coverage, where applicable, prior to study participation.
- Creation of a trust fund to subsidize participants' future excess costs of purchasing coverage through risk pools or other guaranteed-issue programs.

⁴⁶ Jennifer A. Campbell, Health Insurance Coverage: 1998, Current Population Reports, U.S. Census Bureau, Economics and Statistics Administration, U.S. Department of Commerce, October 1999. Some individuals have coverage from more than one source.

Potential Public Policy Options

These are intended to illustrate the range of possible policy options available to address the potential impact of genetic information on the availability of medical expense coverage. Inclusion in this list should not be interpreted as an endorsement by the American Academy of Actuaries.

- Establish high-risk pools, or other similar safety net programs in all states, open to all who are medically uninsurable, including those with significant genetic risks.
- Establish high-risk pools, or other similar safety net programs in all states, open to all those with significant genetic risks.
- Mandate purchase of coverage (to avoid self-selection), then require guaranteed issue and modified community rating in the individual market.⁴⁷
- Encourage the development of insurance for “genetic risks” (to be purchased before testing).
 - ▲ Guaranteed insurability coverage for individuals.
 - ▲ “Excess premium” insurance to cover the additional cost of guaranteed-issue coverage for those developing genetic illnesses.
 - ▲ Specified disease coverage for genetic diseases.

Need for Research

Potential test recipients, physicians, plan sponsors, and insurers are all concerned with, and need information about, the implications of genetic test results for future health and health care expenses. Research focusing not only on survival rates and the probability of future disease, but future health care needs and the availability, effectiveness, and potential cost savings of early intervention, is of great potential benefit. Not only would patients better understand their prognosis, but physicians could improve treatment modalities, and plan sponsors and insurers could better evaluate the appropriateness of covering specific tests, their likely impact on insurance costs, and their potential implications for risk classification in the individual market.

Summary

Information on the health status of individual program participants is not used to determine eligibility for participation in employer-sponsored medical expense plans. However, the process of risk classification is fundamental to a voluntary, individually purchased medical expense insurance market. Risk classification places applicants into groups with roughly equivalent levels of risk, thereby ensuring their premium cost is commensurate with their risk level. Individuals who know, or suspect, they have genetic disorders fear this information could be used to deny or terminate insurance coverage. As a result, some individuals may avoid taking genetic tests that provide potentially beneficial information about their condition, even if that information might help prevention or treatment.

Various programs have been developed to guarantee access to medical expense insurance to those who would otherwise be uninsurable. While most Americans are guaranteed access to some form of medical expense insurance, the cost of coverage varies significantly, and there are still some gaps. Filling those gaps could help reduce the potentially adverse impact of genetic testing on an individual's future ability to purchase medical expense insurance.

While only a minority of Americans receive coverage through the voluntary, individual medical expense market, it plays an important role as a residual market for those who do not have access to coverage through an employer-sponsored or government-sponsored program. In addition, many policymakers have suggested that there might be significant advantages to moving away from an employment-based system of health insurance. As a result, the individual market may have a greater significance than its size might otherwise indicate.

Guaranteeing all Americans access to medical expense insurance, while preserving the viability of a voluntary system of individually purchased insurance, is a difficult but important challenge that policymakers have struggled with for a number of years. Banning the use of genetic tests by health insurers is one policy option often suggested. The impact of a ban on the use of genetic tests would depend on the ban's duration, the scope of the definition of "genetic testing" used, and the cost and predictive power of the tests covered by the ban. A moratorium on some types of tests would cause minimal disruption at first, because relatively few genetic tests are currently available and their predictive power is generally limited. However, a ban on the use of genetic testing could have more severe consequences over time, as genetic technology advances. As tests become more accurate, less expensive, and better able to detect a wide range of conditions, the potential impact of a ban would increase.

A long-term ban on genetic testing has the potential to disrupt the voluntary individual medical expense insurance system, ultimately hurting the American people by making individual insurance more expensive and more difficult to obtain. On the other hand, mechanisms are needed to ensure that everyone has access to needed medical care. For these reasons, the Academy believes that further research should be undertaken on the issues raised by genetic testing. As the public debate continues on how best to face the multiple challenges posed by developing genetic technologies, the actuarial profession, through the American Academy of Actuaries, will continue to assist public understanding of actuarial aspects of this complex issue.

Appendix

Hypothetical Future Scenarios

These scenarios are entirely speculative, and are not intended as projections or predictions of future developments. Rather, they illustrate the significance of several key factors and the wide range of possibilities the future holds. Among the key factors considered are the number of genetic tests available, their unit costs and predictive power, and the availability and cost of treatments for the conditions identified. Also considered are the availability of genetic treatments and the unit cost of those treatments. Roughly speaking, the scenarios progress from one that assumes genetic technology will have only a modest impact on the health care system to one that assumes much more significant changes in our ability to identify and treat disease. We attempt to qualitatively describe the likely impact of each scenario on health plan costs and premiums.

Scenario One

Several dozen tests are developed that identify single-gene abnormalities that lead almost inexorably to serious illness. Taken together, these single-gene abnormalities affect only 1 percent or 2 percent of the general population. Roughly half are treatable; for the rest, only palliative care is available. Unit costs of testing are initially quite high, but drop steadily over time.

Roughly 100 tests are developed that show, to varying degrees, predisposition to diabetes, heart disease, and several of the more common forms of cancer. In general, they have roughly the same predictive power as moderately elevated cholesterol levels for heart disease, or mild obesity for diabetes.

Medical expense programs begin covering tests for those single-gene disorders that are treatable as effective interventions are identified. Testing is covered on a medical necessity basis as determined by family history and other risk factors, or early warning signs of disease. Tests for diseases that cannot be treated are typically not covered except on a diagnostic basis, to confirm the existence of disease once it has been manifested. The medical community generally avoids use of those tests. The cost to health plans (and the consequent impact on premiums) of covering testing for single-gene disorders is mild, due to the relative infrequency of use. Most individuals are covered through employer-sponsored programs. Individual market insurers do not require applicants to undergo genetic testing. However, those who have an identified single-gene disorder generally do not qualify for newly purchased private-market individual medical expense insurance, and must rely on subsidized high-risk coverage. Specialty insurers develop specified disease coverage that pays a lump sum, or monthly indemnity, on first manifestation of one of the “untreatable” single-gene disorders. This coverage must be purchased before any testing.

Screening tests that show a predisposition to disease are gradually accepted as covered expenses when used to further evaluate individuals with other risk factors, such as family history or excess weight. The impact of covering these tests on health plan costs and premiums is somewhat higher, due to broader use of the tests. Private individual market insurers do not require applicants to take these screening tests either. The impact of an identified predisposition depends on the presence of other risk factors, and may result in an increased premium or an inability to qualify for coverage. Those who do not qualify for private coverage, or employer-sponsored coverage, rely on subsidized, guaranteed-issue coverage.

Scenario Two

Several dozen tests are developed that identify single-gene abnormalities that lead almost inexorably to serious illness. Taken together, these single-gene abnormalities affect only 1 percent or 2 percent of the general population. Direct genetic therapy is developed for all of them, generally within a few years

of their identification. Unit costs of testing are initially quite high, but drop precipitously over time. While genetic therapy resulting in a complete cure is available, unit costs for treatment are extremely high.

Roughly 100 tests are developed that show, to varying degrees, predisposition to diabetes, heart disease, and several of the more common forms of cancer. In general, they have roughly the same predictive power as moderately elevated cholesterol levels for heart disease, or mild obesity for diabetes.

Medical expense programs begin covering tests for those single-gene disorders that are treatable as effective interventions are identified. Testing is initially covered on a medical necessity basis as determined by family history and other risk factors, or early warning signs of disease. Pressure from the medical community and the general public leads to mandated coverage of the tests on a broad population screening basis. Treatment is covered. The impact of testing for single-gene disorders on health plan costs and premiums is mild, due to the low unit costs. Covering treatment has a significant impact on health plan costs and premiums, however, due to very high unit costs. Most individuals are covered through employer sponsored programs. Due to the combination of low unit costs for testing, broad medical acceptance, and high predictive power, individual market insurers gradually begin requiring applicants to undergo testing for the most prevalent single-gene disorders. Those who have an identified single-gene disorder generally do not qualify for newly purchased private market individual medical expense insurance until they have been successfully treated, and must rely on subsidized high-risk coverage. Once treatment is complete, affected individuals are considered cured and the condition has no further effect on insurability.

Screening tests that show a predisposition to disease are gradually accepted as covered expenses when used to further evaluate individuals with other risk factors, such as family history or excess weight. The cost impact is somewhat higher, due to broader use of the tests. Private individual market insurers do not require applicants to take these screening tests. The impact of an identified predisposition depends on the presence of other risk factors, and may result in an increased premium or an inability to qualify for coverage. Those who do not qualify for private coverage, or employer-sponsored coverage, rely on subsidized, guaranteed-issue coverage.

Scenario Three

Several dozen tests are developed that identify single-gene abnormalities that lead almost inexorably to serious illness. Taken together, these single-gene abnormalities affect only one or two percent of the general population. Direct genetic therapy is developed for all of them, generally within a few years of their identification. Unit costs of testing are initially quite high, but drop precipitously over time. While genetic therapy resulting in a complete cure is available, unit costs for treatment are extremely high.

The combination of genetic microchips and sophisticated computer models allows the automatic, low-cost screening of tens of thousands of genetic variations and their interactions. They are able to identify predisposition to a wide array of illnesses. In general, they have roughly the same predictive power as do moderately elevated cholesterol levels for heart disease, or does mild obesity for diabetes. Unit costs are relatively low. The tests identify one or more predispositions in most people tested.

Medical expense programs begin covering tests for those single-gene disorders that are treatable as effective interventions are identified. Testing is initially covered on a medical necessity basis as determined by family history and other risk factors, or early warning signs of disease. Pressure from the medical community and the general public leads to mandated coverage of the tests on a broad population screening basis. Treatment is covered. The cost to health plans of testing for single-gene disorders is mild, due to the low unit costs. The cost impact of treatment is significant, however, due to

very high unit costs. Most individuals are covered through employer-sponsored programs. Due to the combination of low unit testing costs, broad medical acceptance, and high predictive power, individual market insurers gradually begin requiring applicants to undergo testing for the most prevalent single-gene disorders. Those who have an identified single-gene disorder generally do not qualify for newly purchased private market individual medical expense insurance until they have been successfully treated, and must rely on subsidized high-risk coverage. Once treatment is complete, affected individuals are considered cured and the condition has no further effect on insurability.

Individualized screening tests to identify a predisposition to disease are gradually accepted as covered expenses, driven largely by consumer demand. The cost of covering these tests is somewhat higher than that of covering screening for single-gene disorders, due to broader use of the tests and somewhat higher unit costs. Unlike tests for single-gene disorders, private individual market insurers do not require applicants to take these screening tests. The impact of an identified predisposition depends on the presence of other risk factors, and may result in an increased premium or an inability to qualify for coverage. Most individuals show a susceptibility to one or more diseases, and it is common for many with identified potentials for future disease to be accepted as standard risks. Those who do not qualify for private coverage, and do not have employer sponsored coverage, rely on subsidized, guaranteed issue coverage.

Scenario Four

The combination of genetic microchips and sophisticated computer models allows the automatic, low-cost screening of hundreds of thousands of genetic variations and their interactions. They are able to predict with a high degree of accuracy the future likelihood of most non-infectious disease other than poisoning. In general, they have very high predictive accuracy. Unit costs are moderate.

Roughly 2 percent to 3 percent of the general population are identified as having single gene abnormalities, for which direct genetic therapy is developed. Genetic treatment of single gene abnormalities is moderately expensive. Direct genetic therapy for conditions arising from the interaction of more than a handful of gene abnormalities is impractical. Where genetic therapy is available, the result is a complete cure.

As consumers realize the predictive power of individualized assessments, they begin demanding access to them. When not covered by medical expense programs, individuals seek them on their own. Pressure from the medical community and the general public leads to mandated coverage of the tests on a broad population screening basis. Treatment is covered. Covering testing has a significant impact on health plan costs and premiums, due to the combination of moderate unit costs and almost universal usage. The cost impact of genetic treatment is moderate, due to high unit costs. Most individuals are covered through employer sponsored programs. Due to the predictive power of these individualized assessments, individual market insurers gradually begin requiring applicants to undergo testing. However, this becomes a largely moot issue, as most individuals have already sought testing for other reasons. Those who have an identified single-gene disorder generally do not qualify for newly purchased private market individual medical expense insurance until they have been successfully treated, and must rely on subsidized high-risk coverage. Once treatment is complete, affected individuals are considered cured and the condition has no further effect on insurability.

The impact of an identified multi-gene disease on the expected cost of traditional treatment varies, and may result in an increased premium or an inability to qualify for coverage. Those who do not qualify for private coverage, and do not have employer-sponsored coverage, rely on subsidized, guaranteed-issue coverage. Those individuals who have no identifiable genetic disease begin seeking very low cost coverage, and are often unwilling to pay for anything other than catastrophic coverage for

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injury or infectious illness. In this case the ultimate character of the market depends on the relative number of these “genetically blessed” individuals. If there are relatively few, then the impact may be relatively small. If they are relatively many, their unwillingness to pay for anything other than minimal coverage may undermine the stability of the market for broad coverage, leading to a voluntary market that only provides catastrophic coverage and the need for a mandatory mechanism to provide for genetically based illnesses.