

GENETIC INFORMATION AND HEALTH INSURANCE

Report of the Task Force on
Genetic Information and Insurance

May 10, 1993

NIH-DOE Working Group on
Ethical, Legal, and Social Implications
of Human Genome Research



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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June 19, 1993

The Honorable Donna E. Shalala
Secretary of Health and Human Services
Washington, D.C. 20201

Dear Secretary Shalala:

On behalf of the U.S. Human Genome Project, we are pleased to transmit the report of the NIH-DOE Task Force on Genetic Information and Insurance entitled *Genetic Information and Health Insurance*.

Genetic Information and Health Insurance assesses the potential impact of new advances in human genetics on the current system of health care coverage in the U.S., and makes recommendations for managing that impact within a reformed health care system. The report provides a new argument for implementing a health care system in which access to health services is not constrained by personal risk underwriting. This argument is grounded in the changing scientific face of health care and the increasing medical utility of genetic information concerning individual health risks. As the Human Genome Project proceeds, it will be increasingly important to ensure that the health benefits made possible through genetic risk assessments can be realized by individuals and families without endangering their health care coverage.

Genetic Information and Health Insurance was prepared at the request of the U.S. Human Genome Project by an independent task force composed of clinical geneticists, health policy researchers, insurance industry policy analysts, and representatives from genetic disease lay organizations. It represents one of the many initiatives under way as part of the Human Genome Project's effort to anticipate and address the ethical, legal and social implications of new advances in human genetics. We believe that this report, begun in 1991, complements the current efforts of the President's Task Force on Health Care Reform, and we recommend it to you as a participant in that initiative.

Sincerely yours,

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Enclosure

This report reflects the substantial contributions of all Task Force members. Two members in the end chose not to support the report.

The following Task Force members support the report:

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The American Council of Life Insurance opposes the report on the grounds that it “directly conflicts with ACLI policy in its overall thrust and specific recommendations.”

The Health Insurance Association of America has concluded that it “should neither oppose or support the final report; that the association's position should be one of neutrality.”

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Executive Summary

One of the ironies in the current health care coverage crisis is that developing more accurate biomedical information could make things worse rather than better.

In the current American health care system, information about an individual's risk of disease plays a crucial role for many people in determining access to health care coverage. This link between the likelihood of needing health care and the ability to obtain coverage for that care has the unfortunate result that those most in need may have the greatest difficulty finding affordable health care coverage. New advances in human genetics are transforming medicine by making available increasing amounts of such information about risk.

Biomedical science and the delivery of health care are being reshaped by advances in our understanding of human genetics. New insights into health and disease, new diagnostic and prognostic tests and the possibility of new therapies reflect significant investments by the public and by private business and are no longer limited to the uncommon disorders traditionally labeled as "genetic diseases." Among the first products of genetic research is information useful in predicting the likelihood that an individual will develop particular diseases, opening the door both to preventive strategies that we would welcome, such as changes in diet and exercise patterns, and to the unwelcome possibility of genetic discrimination.

Injecting information about genetic risks into the current health care system could result in ever more refined risk rating by insurers and ever greater difficulty in finding affordable health care coverage for large numbers of people. At a minimum, people could be discouraged from obtaining genetic information that might be useful in disease prevention and early treatment or for case planning and management because that same

information could jeopardize their access to health care coverage in general, or to treatment for a condition excluded from coverage because it was "preexisting." Under other circumstances people might be compelled to provide genetic information as a condition of obtaining affordable health care coverage. Genetic risk information carries an additional, wider burden because information about an individual's genetic health risks may also be information about the risks of children, parents, brothers, sisters, and other relatives.

One suggested approach—providing special protection for genetic information—is unlikely to succeed. This special protection has been suggested because of the relevance of genetic information to family members and its implications for reproductive choices, potential discrimination and stigmatization. Genetic privacy ought to be vigorously protected; however, other varieties of health related information are equally sensitive. Furthermore, as a practical matter, genetic information is not segregated from other health related information in, for example, medical records.

Special protection for genetic information is also difficult to enforce because of the "genetic revolution" in medicine. Diseases increasingly are coming to be seen as having both genetic and non-genetic components, making it ever more difficult to classify health related information as wholly genetic or non-genetic. The standard personal medical history, for example, is a rich source of genetic information. Policies intended to protect genetic privacy will need to address the privacy of health related information in general. If we want strict standards to safeguard genetic information, then those same standards will have to extend to all health related information. The Task Force considered these factors carefully.

In anticipation of fundamental reform in the financing and delivery of health care in the U.S., the Task Force on Genetic Information and Insurance offers the following recommendations. The recommendations concern health care coverage and should not be applied uncritically to other forms of insurance, such as life or disability income insurance.

- Information about past, present or future health status, including genetic information, should not be used to deny health care coverage or services to anyone.**
- The U.S. health care system should ensure universal access to and participation by all in a program of basic health services* that encompasses a continuum of services appropriate for the healthy to the seriously ill.**
- The program of basic health services should treat genetic services comparably to non-genetic services, and should encompass appropriate genetic counseling, testing and treatment within a program of primary, preventive and specialty health care services for individuals and families with genetic disorders and those at risk of genetic disease.**
- The cost of health care coverage borne by individuals and families for the program of basic health services should not be affected by information, including genetic information, about an individual's past, present or future health status.**
- Participation in and access to the program of basic health services should not depend on employment.**
- Participation in and access to the program of basic health services should not be conditioned on disclosure by individuals and families of information, including genetic information, about past, present or future health status.**
- Until participation in a program of basic health services is universal, alternative means of reducing the risk of genetic discrimination should be developed. As one step, health insurers should consider a moratorium on the use of genetic tests in underwriting. In addition, insurers could undertake vigorous educational efforts within the industry to improve the understanding of genetic information.**

(* We use the phrase "program of basic health services" to describe the array of services that would be available to all after implementation of major health policy reforms, such as those being considered by the President's Health Policy Task Force. We explicitly reject all connotations of "basic" as minimal, stingy, or limited to such services as immunization and well child care. A program of "basic" health services could encompass a broad range of care for those most in need.)

Introduction

One of the most important consequences of contemporary human genetic research will be a vast increase in the kind and amount of genetic information available for and about individuals. Genetic information that aids in predicting a person's risk of disease could be very useful to that individual, who might take measures to prevent the disease or to lessen or anticipate its consequences. At the same time, however, such predictive genetic information could, like other forms of information that help to predict the likelihood of disease, disability or death, enter into decisions whether to seek (on the part of individuals) and whether to sell (on the part of insurers) health, disability and life insurance.

The Human Genome Project, an international effort, supports research on human genetics that will enhance the amount and quality of genetic information. In order to promote constructive uses of the fruits of the Human Genome Project, and to minimize its potentially harmful consequences, a Working Group on Ethical, Legal and Social Issues was established. That Working Group created a Task Force on Genetic Information and Insurance composed of representatives of organizations with interest in the issue, along with a variety of experts on facets of the problem. The Task Force's membership is listed as Appendix A. The Task Force began its work in May 1991 and was given two years to complete this report. Our mandate was to establish facts relevant to the problem, clarify the issues and the stakes, and make recommendations on how best to handle the growth of genetic information in relation to insurance. A great diversity of interests is represented among our members. We had hoped to issue a unanimous report. In the end, that was not possible, as the organizations represented by two of our members chose, respectively, to withdraw from this report (American Council of Life Insurance), and to adopt a stance of neutrality (Health Insurance Association of America). For the sake of accuracy and

completeness, it must be noted that this report reflects the substantial contributions and considerable efforts of each and every member of the Task Force.

Each recommendation is discussed in detail in the body of this report. Because of its importance in framing the report, one particular conclusion deserves to be mentioned in this introduction. As a practical matter, it will become increasingly difficult to deal with genetic information as special and separate from other forms of health-related information because diseases are increasingly understood as having both genetic and environmental components. It is the judgment of this Task Force that the problems created by predictive genetic information cannot be addressed adequately within the current health care system. Although there are many additional reasons to support restructuring the American health care system, the problems associated with increasing genetic information expose inequities and perversities in the current system, and would exacerbate them unless the system itself is altered in certain fundamental respects.

It should be noted clearly that the Task Force's conclusions and recommendations focus primarily on health care. The characteristics of life and disability insurance in the contemporary U.S., along with the differences in the social purposes underlying each of these types of insurance, made the Task Force unwilling to generalize our findings and recommendations beyond health care coverage. (See Appendix C)

The Task Force recommendations should be taken as a package (except for Recommendation Seven which deals with the interim before the other six recommendations are implemented). Failure to implement one or more of these recommendations will leave gaps through which the problems that inspired this report could reemerge. If we desire a health care system that does not erect barriers to participation for people whose genes place them at increased risk for disease,

then nothing short of the comprehensive changes recommended in this report is likely to reach our goal.

This report will describe the nature of the problem created by the prospect of a dramatic increase in predictive genetic information, present the recommendations of the Task Force, describe the background issues that determine the context for the problems addressed here, and note a set of issues deserving further consideration. The report contains appendices identifying the Task Force members, describing its charge (Appendix B), and explaining the relationship of this report to life and disability income insurance, which are not further addressed here.

The Human Genome Project

The Human Genome Project is an international effort to construct a finely detailed map of all of the human chromosomes and to spell out the sequence of the 3 billion DNA base pairs which our 24 unique chromosomes contain. Biomedical researchers will be able to use this information to speed isolation of human genes, thus providing a potentially useful tool for unraveling the complexities of human development, physiology and disease.

Many aspects of the Human Genome Project are unprecedented for a federally organized, publicly supported biomedical research project. First, the organization of the Human Genome Project within the United States involves two Federal agencies, the National Institutes of Health and the Department of Energy, that collaborate in its administration. Second, the Human Genome Project is international in scope, with many countries, including France, the United Kingdom, Japan and Canada, participating. Finally, a portion of the Human Genome Project's resources (3-5%) is being devoted to addressing the ethical, legal and social implications of genetic research and technologies. The work of the Task Force on Genetic Information and Insurance is part of this program.

development of tests that will provide health-related genetic information. In the past five years, more than fifty new tests for genetic conditions have been developed. In addition to tests for well-known genetic diseases such as muscular dystrophy and cystic fibrosis, genetic tests for susceptibility to such common diseases as cancer and heart disease are also in development.

B. Genetic information may become increasingly useful in predicting health-related outcomes such as the likelihood of illness or early death.

There is a gene carried by one woman out of every two to four hundred that increases her chance of developing breast cancer to eighty-five percent during her lifetime. Once the gene is isolated, a test can be developed. Another test that identifies a gene that

The Nature of the Problem

In its inquiries, the Task Force identified nine factors that were critical to understanding the problems posed by genetic information and insurance, and that shape our recommendations.

A. A wave of new genetic information is coming, information that is relevant to health and disease.

Until very recently, genetic information useful in predicting the likelihood of disease was limited to such things as a person's family medical history or the occasional test for an underlying genetic condition, such as the sweat test for cystic fibrosis. Current research in the basic sciences, advances in clinical medicine, and technology development are accelerating the pace of

greatly increases the risk of colon cancer is being refined. As similar tests for genetic predictors of other common diseases are developed, many people may learn that they are at genetic risk for one or more diseases.

As accurate and affordable means for providing information about health-related genetic risks become available, they are likely to filter into the health care system. Information about an individual's susceptibility to an array of diseases can be useful in identifying what health-related behaviors to avoid or pursue. Such information could also indicate who should receive more frequent or intensive screening for diseases such as breast or colon cancer. Genetic risk prediction could be useful to individuals, as well as providing public health benefits such as a

reduced burden of illness and more efficient use of health resources.

C. In the current American health care system, risk information plays an important role for a significant number of people in determining access to health care coverage.

Insurance companies use medical information that predicts risks of illness and death in choosing which individuals and groups they will insure and at what price. Insurers use such information to project claims, to deny or limit coverage for risks they deem too high, and to prevent applicants from concealing known risk factors.

Genetic information is included in the medical data insurers use in underwriting, primarily obtained through the application form and the individual's medical record. So far, the genetic information obtain-

able from these sources has been limited. With the increase in genetic information promised by research in human genetics, the volume and variety of genetic information available to insurers will increase, as will the likelihood that the barriers to adequate health care coverage will grow for a substantial number of Americans. In the past, medical histories and conventional genetic diagnostic techniques have resulted in limitation or denial of insurance coverage or claims for the relatively small percentage of the population

burdened by debilitating conditions such as cystic fibrosis and Huntington's disease. New genetic tests in the context of risk underwriting by health insurers are likely to exacerbate an already severely troubled health care system.

Genetic Testing and Genetic Information

Genetic information about a person's or a family's health conditions and health prospects can be obtained in many ways, including but not limited to genetic tests.

Genetic information can be inferred from a knowledge of a family's medical history. Although family history alone cannot usually predict which family members will actually develop the disease and which will not, it can be used to assess genetic risk. As the number of common disorders (cancer, heart disease) found to have a genetic component increases, the number of people affected by genetic information will rise. Finally, genetic information about an individual may be gleaned by recognizing its phenotype, or clinical signs.

The most direct approach to obtaining genetic information is the use of genetic tests. Genetic tests can be carried out with a variety of approaches. First, sophisticated molecular genetic analyses can lead to the direct or indirect detection of a gene that is mutationally altered (e.g. cystic fibrosis or Adult Polycystic Kidney Disease). Second, some genetic conditions are in part manifested as an alteration of normal metabolism (e.g. hypercholesterolemia) or as some other detectable physiological abnormality (e.g. sickle-cell anemia). Biochemical and other techniques can be used to detect these traits. Third, use of the microscope to detect changes in the number, structure or integrity of chromosomes can lead to prediction of health problems (e.g. Down's Syndrome or Fragile X Syndrome).

All of these approaches yield genetic information that can be used in the assessment of health risks by insurance underwriters.

At present, medical underwriting of individuals affects a substantial minority of health insurance applicants, principally those applying for individual or small group policies. In the near future, predictive genetic testing is likely to cause problems in the medium and large group health insurance markets as well. The rapidly rising cost of employee health care benefits has pressured employers to find ways to save money. Group plans can be structured to anticipate and limit coverage for particular conditions such as expensive genetic disorders. The large number of employers who have moved to self-insured plans can change their ben-

efit packages at will in order to reduce costs, so that entire categories of health conditions can be left uncovered.

D. Genetic information has implications for family members as well as the individual.

When people learn that they have a gene that places them at increased risk for certain diseases, that information is also directly relevant to their biological relatives. Except in the rare instances where the gene in that individual was the result of a spontaneous

mutation, other family members may also have the gene and therefore be at increased risk.

The fact that genetic information concerns more than just the individual has implications for confidentiality (see G. below). It also means that genetic information about increased risk for one person that affects his or her access to health care could also affect access to health care for that person's family members should the information be passed eventually to potential insurers, as it might in taking a medical history.

E. The health benefits expected to flow from increased genetic information will be lost to the extent that people are discouraged from obtaining that information for fear of losing health care coverage.

When people know that insurers can obtain their medical records, including genetic information, and that such information could affect adversely their access to health care coverage, they may withhold information from their health care provider or refuse tests that might have substantial value in diagnosis, therapy,

prevention, or early detection and treatment of disease.

Research into genetic diseases may be hampered as potential subjects are told that learning you are at increased genetic risk may jeopardize your access to health care coverage.

Genetic counselors are becoming increasingly aware of the implications of genetic knowledge, and may feel obliged to give similar warnings to people who are considering undergoing genetic tests. This has already been seen in experimental programs for pre-symptomatic genetic testing for such maladies as Huntington disease.

F. Under certain circumstances people may be compelled to provide genetic information, including undergoing genetic testing, as a condition of obtaining health care coverage.

If information about health risks, including genetic information, continues to be used in determining who can and who cannot obtain

health care coverage, it is likely that in time people will be asked to provide information about their genetic risks to insurers. The scenario may unfold in this fashion: as genetic risk information becomes more pertinent to people's lives, and the

What is underwriting?

Medical underwriting is the process by which insurance companies determine whether an application for insurance by a small group, family or individual represents an acceptable risk. This determination is based on the type and size of the proposed contract and a review of the financial, health, lifestyle and other characteristics of the applicant. The potential health impact of these characteristics is compared with other applicants to evaluate if he or she is expected to generate more claims than the average person. Using this and other considerations, the underwriter then classifies the risk as preferred, standard, substandard, or declined. Most large group policies are not underwritten because the risk (the likelihood of paying out claims) can be spread among more people.

Applications are rated substandard when the underwriter determines that early claims can be expected. Consider, for example, an applicant who has suffered a heart attack. The underwriter would attempt to predict, on the basis of information about the severity of the heart disease and risks for further illness, what premium the client should be charged. This premium would be based on estimations of the costs of potential health problems to the insurance company and its other policy holders. When the risk of early claim is above some preset limit, the policy application is declined.

At present, insurance companies in the United States do not themselves perform genetic tests for underwriting. The reasons cited are high cost, the uncertain predictive value of many genetic tests, and a lack of genetic counseling facilities. However, records of DNA tests that have been done by others are important to underwriters. Genetic information may be obtained from medical records or indicated by certain codes in files from the Medical Information Bureau. Like other laboratory tests, the results of DNA tests may inform the underwriter of an increased risk of death or disease. If these results are obtained by the insurance company, it may lead to a substandard or declined application status. On the other hand, if results of such tests are known by the applicant and concealed from the insurer, insurance contracts may be voided and adverse selection may result.

cost of obtaining that information decreases, more people will seek it. Knowledge about their individual risks may affect people's decisions whether to seek health care coverage. Some insurers, fearing adverse selection and perhaps also recognizing an opportunity for new products, may solicit or require genetic information from some of their customers. Other insurers may be forced by competitive market pressures to begin likewise to seek genetic information.

Good clinical practice requires obtaining informed consent before creating information about an individual's genetic risk. If risk underwriting remains a crucial feature in determining access to health care coverage, and genetic testing technology develops as expected, then it is likely that many people will be pressured to provide

genetic information. Informed consent may continue to be observed in name, but forcing people to choose between consenting to

provide genetic information versus being denied access to health care coverage would jeopardize the voluntariness of informed consent for genetic testing. Individuals may still have a choice, but when refusing to consent leads to unacceptable consequences, their freedom in practice to refuse to consent is severely constrained.

G. Confidentiality is important for all medical information. In the case of genetic information, the importance of confidentiality is heightened because of its implications for other family members, its consequences for reproductive decisions, a history of misuse of genetics, and the prospect of genetic stigmatization.

Information about one's health is generally regarded as sensitive. Information about one's genes in relation to health is especially sensitive for several reasons. First, genetic information about an individual is also information about that per-

son's family. Second, genetic information may affect profoundly people's decisions about having children. Third, there is a long and

Cases

- 1) One woman was denied health care coverage because her nephew had been diagnosed as having cystic fibrosis and she had inquired whether she should be tested to see if she was a carrier. After she was tested and found to carry the gene that causes CF, she was informed that neither she nor any children she might have would be covered unless her husband was determined not to carry the CF gene. The woman went for several months without health insurance as a consequence of seeking genetic information about herself.
- 2) When a man was diagnosed as having Huntington disease, his insurer denied coverage on the grounds that it was a "pre-existing condition" despite no previous diagnosis of Huntington having been made. After protest, coverage was granted, but not for the custodial care he needed most. When his wife applied for a supplementary insurance policy, coverage for three conditions was excluded. One of the exclusions concerned her family's risk of colon cancer, despite regular checks that had shown no signs of incipient disease for her.
- 3) It has been several years since another man's son was diagnosed with a serious genetic disease. The son is now severely disabled. The man participates in his company's annual negotiations with insurers bidding for his firm's business. One insurer dropped the firm after failing to exclude coverage for the boy as a "pre-existing condition." Bids from other companies have noted that rates would be much lower if coverage for the man's family was dropped. Premiums have increased an average of 40% a year. The man believes he will not be promoted because of his son's illness. The prospect of losing coverage for his son deters him from taking a job with another firm.
- 4) An eight-year-old boy began to show symptoms of what was eventually diagnosed as a severe case of Tourette Syndrome. The specialist at his HMO was unable to diagnose or treat effectively his condition, and actively opposed consultation with experts outside the HMO. On their own, the family took the boy to specialists who were able to diagnose his condition properly, and recommend highly effective treatment for it. The child is doing very well, but went through five needless hospital stays and the HMO wasted tens of thousands of dollars because of a lack of flexibility in dealing with a rare disorder.

Cases 1 through 3 were abstracted from a study prepared by Paul R. Billings, M.D., and are available from the NCHGR by its title "A Study of Genetic Discrimination."

sad history of eugenics in American public policy, often based on pseudo-science. Eugenic arguments continue to be offered today, and could be directed against people thought to carry "defective" genes. Fourth, there is ample evidence that some individuals labeled as carrying a "defective" gene are stigmatized, suffering a loss of social and economic opportunities.

H. Insurers are concerned that if they are denied access to genetic information possessed by an applicant, underwriters will be at a disadvantage in attempting to assess the likely costs of claims filed by that applicant, a phenomenon known as "adverse selection."

Insurers worry that applicants who know they are at high risk of disease, because they have predictive genetic information to that effect, will attempt to purchase health care coverage at a price that would not cover their claims. If such a phenomenon happened on a wide scale, the likely result is that the price of coverage would rise for all policy holders.

I. For policy purposes, it will become increasingly difficult to distinguish genetic from non-genetic diseases, and genetic information from non-genetic information.

Recognizing that our genes affect many common diseases not previously thought of as genetic will transform the scope and meaning of terms such as genetic information, genetic test, asymptomatic condition, presymptomatic condition, and genetic predisposition to disease.

Important and common diseases are coming to be understood as a complex mixture of genetic and non-genetic factors. Now that cancer, for example, is seen as a result of multiple genetic changes, some of which may be inherited, others caused by toxic chemicals, viruses, radiation, or random mutation, it is neither responsible nor accurate to refer to cancer as simply genetic or non-genetic. Similarly, as we come to understand that a person's serum cholesterol level, and presumably his or her risk of heart disease, depends on a number of genes, and not

merely one's diet or exercise habits, we will not be justified in thinking of heart disease as simply genetic or non-genetic. Instead, cancer and heart disease, as other diseases, will come to be seen as the outcome of a complex set of interactions of both genetic and non-genetic factors.

Just as with diseases, much information about health risks will be seen to reflect both genetic and non-genetic factors. Although certain pieces of health risk information will continue to be seen as straightforwardly genetic—whether one has the gene for Huntington disease—or non-genetic—how many cigarettes per day one smokes—much significant information about health risks will defy such easy categorization. Cholesterol levels, again, are an example.

In addition to the increasing difficulty in categorizing diseases and some forms of health risk information as genetic versus non-genetic, it is comparably impractical to separate genetic from non-genetic information in the principle source of such information for insurance underwriters—the medical record. In response to insurance company requests for authorized disclosure of medical risk information, physicians routinely have their staff copy and send the entire medical record rather than extracting the pieces of information specifically requested by the insurer. Although it might be possible to ask physicians to keep certain types of genetic information physically separate from the remainder of the medical record, much of the information in the record about risk factors, diseases, diagnostic tests and treatments will in fact reveal genetic information to the astute reader of that record. We conclude that it is unrealistic to believe that insisting on physical segregation of genetic from non-genetic information in the medical record would in practice keep that information from underwriters. Nor would it be an effective means of assuring that people with genetic health risks have access to health care coverage.

Recommendations

1. Information about past, present or future health status, including genetic information, should not be used to deny health care coverage or services to anyone.

Explanation. This recommendation is intended to cover all providers of health care coverage including self-insuring employers, private insurers, and public agencies. (See box on "Self-insuring Employers and ERISA.")

Rationale. Our current system erects barriers to health care coverage for people most likely to need it. As information, including genetic information, that predicts individuals' health risks becomes more plentiful, accurate, and inexpensive, those barriers to access will continue to grow, especially for those with the greatest need. In light of the widely shared conviction in the United States that health care ought to be available to those who need it, this would be a perverse result.

Also, the current health care system contains disincentives for people to obtain information about their health risks, including genetic risks. The individual and societal benefits that could be gained by providing genetic information might be forgone because people would be frightened that they would have diminished access to health care coverage if they learned that they were at risk of disease.

2. The U.S. health care system should ensure universal access to and participation by all in a program of basic health services* that encompasses a continuum of services appropriate for the healthy to the seriously ill.

(*We use the phrase "program of basic health services" to describe the array of services that would be available to all after implementation of major health policy reforms, such as those being considered by the President's Health Policy Task Force. We explicitly reject all connotations of "basic" as minimal, stingy, or limited to such services as immunization and well child care.

A program of "basic" health services could encompass a broad range of care for those most in need.)

Explanation. In a system of universal access and participation, all members of the community that is the United States of America would be included and would participate in the health care coverage system. No member of the community would be denied access to an appropriate program of basic health services, and all members of the community would participate in the system's financing.

Rationale. The only practical and effective way to prevent discrimination on the basis of genetics in health care is to implement a program that provides access for all to a program of basic health services. In order to guard against the possibility of adverse selection in which individuals know of their health risks but coverage providers are denied that information, participation as well as access should be universal. A program of universal access to and participation in a program of basic health services would also mitigate or eliminate other social problems created by our current patchwork, risk-based system such as job-lock, caused by fear of losing health care coverage if one changes employers.

3. The program of basic health services should treat genetic services comparably to non-genetic services, and should encompass appropriate genetic counseling, testing and treatment within a program of primary, preventive and specialty health care services for individuals and families with genetic disorders and those at risk of genetic disease.

Explanation. This recommendation asks for comparable, not special, treatment for genetic conditions with respect to conditions traditionally regarded as non-genetic. It acknowledges the importance of genetic counseling as well as testing and treatment, and underscores the significance of primary and preventive, as well as specialty, health care services.

Rationale. As we come to understand the contribution of genetics to many common diseases, the historical pattern of providing lesser coverage for diseases traditionally regarded as genetic becomes ever more difficult to justify. Nor would a preference in favor of genetic diseases be any more defensible, even if we could continue to make firm distinctions between genetic and non-genetic diseases, itself a very dubious assumption. Whatever ethical justification exists for providing access to health care in accordance with legitimate need for health care, it applies with equal force and cogency to genetic and non-genetic diseases. Any ethically defensible program of basic health services should encompass those genetic and non-genetic services that enhance lives and ease suffering at reasonable cost.

Measured by their impact on people's lives, services such as counseling, primary and preventive care often have as great as or greater value than specialist services. Effective treatment for genetic disease might be as mundane as obtaining and fitting leg braces for a child who has difficulty walking. Such services should be judged by the same criteria of impact, effectiveness and cost that are applied to technologically sophisticated specialty services, and all other components of the program of basic health services.

Note. Competent diagnosis and treatment of certain rare conditions—genetic and non-genetic—may require consultation with

providers who are not members of the local provider network. The nation's health care system must be flexible enough to provide such care when it is warranted.

Basic Health Services versus Supplementary Services

Discussions about the likely direction of health care reform in the U.S. suggest that a system will emerge in which a program of basic health care services will be available to all, without respect to existing or predicted disease, employment status, or other factors that make health care coverage unattainable for many today. Alongside this program of basic health care services may exist a supplementary system which would be available to those who wanted and could afford such additional coverage.

The Task Force has no objection in principle to such a mixed system, as long as the program of basic health care services provides adequately for the genuine medical needs of people. If needed and appropriate genetic services and health care for genetic diseases are not included in the program of basic health services, then the concerns about unfairness and genetic discrimination that motivated the work of the Task Force will simply migrate to the supplementary programs.

It cannot be emphasized too firmly that the program of basic health services must respond adequately to the health care needs of the American people, or the ethically troubling features of our current system will reappear in the market for supplementary coverage.

4. The cost of health care coverage borne by individuals and families for the program of basic health services should not be affected by information, including genetic information, about an individual's past, present or future health status.

Explanation. The information referred to in this recommendation includes surrogate markers for genetic risk such as family history, ethnicity and clinical test results. Care must be taken that market strategies—such as seeking new plan members only among relatively healthy populations—do not achieve by indirect means the risk segmentation which would be prohibited

by the recommended elimination of risk underwriting for health care coverage. Also, this recommendation refers to the program of basic health services, and not to the pricing of supplemental coverage. (See Box on "Basic Health Services vs. Supplementary Insurance.")

Rationale. This follows from and is a further specification of Recommendations 1 and 2. In addition to outright denial of coverage, or exclusion from needed services, genetic information could be used in pricing policies. If people with genetic or other characteristics that made them more likely to need health care found that care priced out of

reach, the net effect, in diminished access to needed care, would be unacceptable. The same criticism holds for surrogate methods of marketing or pricing care to individuals or groups that select those with fewer risks and lower projected costs. It should be noted that the system we propose—no risk underwriting, with universal participation—effectively eliminates adverse selection as a problem for health insurers within the program of basic health services.

The Task Force recognizes that health information about groups of individuals, including genetic information, may be useful to the organizations that finance and provide health services by allowing them to anticipate and manage the delivery of needed services. However, this use of aggregate health information should not be permitted to lead to denying needed services to individuals, or to the inappropriate release of information about identifiable individuals.

5. Participation in and access to the program of basic health services should not depend on employment.

Explanation. Except for Government programs such as Medicare and Medicaid, most Americans get their health care coverage through employers. Though employers could remain as major financiers of health care coverage, no one should be in jeopardy of losing coverage by becoming unemployed or by changing employers.

Rationale. Tying health care coverage to employment as closely as our current system does has several disadvantages. Many people who are seriously ill with genetic or other medical conditions are too ill to be employed. Others who now have employer-provided health care coverage are denied coverage for treatment of their illnesses because they fall into the category of "pre-existing conditions." Under the current system that requires many employers to bear all or part of the costs of greater health care needs of their employees, employers are discouraged from hiring people with chronic diseases and disabilities requiring medical treatment, including illnesses and disabilities

attributed to genetic factors. Assuring people that they could take another job without forfeiting temporarily or permanently their health care coverage could also relieve the phenomenon of "job-lock" and could contribute to a more efficient labor market.

6. Participation in and access to the program of basic health services should not be conditioned on disclosure by individuals and families of information, including genetic information, about past, present or future health status.

Explanation. This Recommendation does not address genetic screening mandated by law or forensic genetic testing such as DNA "fingerprinting." Nor does this Recommendation prohibit the reasonable use of genetic information in the management of individual patients, or in aggregate form for facility, personnel, or other risk management, policy planning, or research purposes.

Rationale. People should not be compelled to disclose genetic information about themselves as a condition for receiving appropriate health care services. In most cases, people will choose to follow the advice of their health professionals and disclose such information. People may feel less need to conceal genetic information in a health care system such as the one we recommend in which existing or predicted disease does not create barriers to health care coverage. In any event, the sensitivity of genetic information and the importance Americans historically place on privacy and self-determination argue strongly for a policy that does not hold access to health care hostage to one's willingness to reveal or to discover intimate facts about oneself.

7. Until participation in a program of basic health services is universal, alternative means of reducing the risk of genetic discrimination should be developed. As one step, health insurers should consider a moratorium on the use of genetic tests in underwriting. In addition, insurers could undertake vigorous educational efforts within the industry to improve the understanding of genetic information.

Factual Background

A. The Increasing Scope and Impact of Genetic Information

Rapid advances in molecular genetic research will make genetic information increasingly available in the next five to 10 years. These techniques have already shown that genetic mutations can affect susceptibility to heart disease, lung, breast, and colon cancer, insulin-dependent diabetes, and Alzheimer disease. In the near future, genetic testing is likely to be available for risk of colon cancer (Peterson et al., 1991) and for breast cancer as well (Biasecker et al., 1993). Additionally, we may see genetic risk assessment for some forms of heart disease, neurodegenerative disorders, and early onset dementias. (Ostrer, et al., 1993)

The technology necessary to analyze and to assimilate genetic information is advancing rapidly as well. Ten years ago, direct DNA testing was virtually impossible; today, the use of DNA probes, genetic markers, and the development of polymerase chain reaction (PCR) have made it possible to detect both single and multiple gene mutations that can cause or contribute to disease.

Improvements in automated sequencing and information processing also have begun to lower the cost of genetic testing. The largest components of current costs are personnel and licensing fees, but automated sequencing will reduce personnel costs considerably. (Gilbert, 1991) Development of panels of genetic tests, which might be done in a single cycle like automated multiple blood

assays, will increase the volume of genetic information attainable per unit of cost. Ultimately, basic research on the pathophysiology of genetic components of disease will allow cheaper protein product and enzyme tests to be substituted in some cases for molecular genetic tests. (Holtzman, 1989)

For the most part, routine use of genetic tests has been limited to detecting fetal abnormalities, newborn screening, and carrier screening to assess reproductive risk for

populations at high risk for specific disorders. However, as tests become available for more common conditions, such as breast cancer, and as the cost of testing decreases, demand for and use of diagnostic tests is expected to increase. (Holtzman, 1989)

The availability of new genetic tests is likely to result in expanded newborn screening and pre-conception genetic testing. Non-invasive methods of fetal testing (such as recovering fetal cells from maternal blood samples) may encourage more frequent prenatal testing by lowering both the risk and the cost of testing.

Children and adults may be tested for genetic risk factors for an increasing variety of diseases, and approaches to health care may shift more toward preventive strategies and earlier medical intervention or therapeutic regimens. (Ostrer, et al., 1993)

Genetic information about an individual has implications for that person's family. Certain forms of genetic testing, such as linkage analysis, require participation of multiple family members from more than one generation. If family members refuse to cooperate the analysis cannot be done.

Conditions for which specific genes have been recently identified

<i>Disease</i>	<i>Year</i>
Huntington disease	1993
Neurofibromatosis type 2	1993
Adrenoleukodystrophy	1993
Amyotrophic lateral sclerosis	1993
X-linked agammaglobulinemia	1993
Menkes syndrome	1993
Norrie syndrome	1992
Lowe syndrome	1992
Myotonic dystrophy	1992
Aniridia	1991
X-linked Kallmann syndrome	1991
Familial polyposis coli	1991
Fragile X	1991
Neurofibromatosis type 1	1990
Wilms tumor	1990
Cystic fibrosis	1989
Retinoblastoma	1986
Duchenne muscular dystrophy	1986
Chronic granulomatous disease	1986

Pressure to participate, particularly if confirming a genetic diagnosis is crucial to an individual's treatment, can produce serious family distress. (Wiggins et al., 1992)

Many genetic tests do not require active participation of other family members. Nevertheless, one person's test results may have implications for family members who would prefer not to know or are not prepared to receive. Family members who have not chosen to be tested, including those who have refused testing, may learn they are at genetic risk without the benefit of counselling to help them fully understand the meaning of the test results. This potential increase in burdens on family members as a result of genetic tests must be considered when determining how such tests should be used and who should have access to the results.

B. Health Care Financing

Health insurance in the U.S. serves two major purposes—to protect individuals and families from unexpected financial loss due to illness or injury and to finance their basic health care needs. Health insurers charge each of their policyholders a premium, pool the premiums, and use the sum to pay for claims. They base premium rates on the probability of illness or injury, the expected dollar value of the loss, and the costs of administering the policy. (OTA, 1988)

At the end of 1991, approximately 212 million Americans or 85 percent of the civilian non-institutionalized population of 248.7 million, had third-party coverage for health care expenses. Fifteen percent were uninsured. Twenty-seven percent of the population had public coverage (Medicare, Medicaid, or CHAMPUS), and 72 percent had private insurance. (Some people have both public and private coverage, for example, Medicare plus a "medigap" policy.) Of the 178 million individuals privately insured, over 94 million are covered by employers or group plans, and almost 10 million had individual coverage. (HIAA, 1993)

For the most part, health care benefits and insurance are provided privately through commercial insurance companies, non-profit

insurers (Blue Cross/Blue Shield), health maintenance organizations (HMO), preferred provider organizations (PPO), or directly by self-insured employers. Non-profit plans cover approximately 68 million people. About 104 million people obtain insurance from commercial plans or through their employers' self-funded plans. HMOs enroll approximately 39 million members. (GHAA, 1992)

Non-profit Plans. Blue Cross (hospital service reimbursement) and Blue Shield (physician service reimbursement) were established in the 1930s and provided the first private health insurance in the U.S. Currently, 71 plans, each covering a specified geographic area, offer insurance policies to groups and individuals. (HIAA, 1993)

Access to coverage varies among the plans. Nineteen of Blue Cross and Blue Shield plans, mostly in the Northeast, have open enrollment periods for individuals under age 65 without regard to medical conditions. Four of those plans are required by state law to be the insurer of last resort, while the remainder do so voluntarily. Frequently, individuals seeking insurance in open enrollment plans find their premiums to be quite high because of the number of persons with costly medical problems who are insured by those plans. Those who obtain insurance through open enrollment are often confronted with less comprehensive benefits, higher premiums, waiting periods, and pre-existing condition exclusions. (OTA, 1988)

Commercial Insurers. Unlike Blue Cross/Blue Shield, commercial insurers are not limited to specific locations, nor have they traditionally offered open enrollment. Commercial insurers offer group insurance to employers based on the firms' past claims (experience rating). For individuals and small groups who apply for coverage, commercial insurers evaluate risk based on medical history information requested on the application or obtained from the applicant's medical records.

HMOs and Other Managed Care Plans. HMOs and other managed care plans differ from traditional insurance plans in several

significant ways. First, they provide a broad range of health services at a fixed fee as well as providing insurance against catastrophic loss. Second, most HMOs follow and meet federal qualification standards. These regulations pertain to premium rates, pre-existing conditions, underwriting, and other aspects of insurance provision. Ninety-five percent of HMO members belong to federally qualified plans. (GHAA, 1992)

Though 10 to 15 percent of persons who are commercially insured obtain coverage as individuals, a disproportionately small number of HMO members join as individuals. According to the Office of Technology Assessment, "no more than 4 percent of non-Medicare HMO members enroll as individuals. Many of these 'self-payers' are 'conversions' (i.e., former group members who have converted to individual enrollment because of a change in employment or marital status)." (OTA, 1988)

Self-Insurance. Employers who self-insure directly assume some or all of the cost of employee care rather than pay premiums to a third party insurer. Self-insurance allows businesses to retain control over funds they have allocated to health financing. It also allows them to escape state-mandated minimum benefit requirements and to avoid insurance premium taxes that, among other things, subsidize state sponsored high-risk insurance pools. Most firms that self-insure do not administer health benefits themselves, but rather contract with commercial or non-profit insurance companies or third party administrators. (Bobinski, 1990)

The percentage of large firms that self insure has increased significantly during the last decade—from about 20 percent in 1980 to about 65 percent in 1988 according to a GAO report. (GAO, 1990)

Self-insured employers directly assume the risk of loss and pay the health costs of their employees, in some cases purchasing catastrophic loss coverage from commercial insurers to protect against claims of a devastating magnitude. Such employers, therefore, have an additional, direct incentive to minimize the health costs of their employee benefit plans. Neither the Americans with

Disabilities Act of 1990 (ADA) nor the Employee Retirement Income Security Act (ERISA) provides employees adequate protection from coverage exclusions or limitations based on genetic risks or disorders. ERISA affirmatively prohibits states from regulating self-insured employee benefit plans. State regulations designed to ensure adequate health insurance for employees of commercially insured employers provide no protection to employees of self-insured organizations. (Ostrer, et. al, 1993)

Public Plans. For a variety of reasons, many Americans cannot obtain access to health care through private insurance plans. The U.S. relies on Medicaid, Social Security, and Medicare to finance health care for those who are poor, disabled, or aged. Although often referred to as "insurance," these programs are in reality government sponsored social insurance financed through Social Security and other mandatory taxes rather than commercial contractual agreements based on premiums. These public social insurance programs do not use risk selection and classification. The federal government also finances the health care of members of the military and their families through the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS).

C. Health Insurance Markets

During the 1940s the U.S. government used tax exemptions to encourage employers to offer health insurance as part of employee benefit packages. Employment-based health care benefit plans now provide some coverage for the majority of working Americans. Approximately 10-15 percent of commercial health insurance is sold to individuals. (OTA, 1988)

Individual Policies. Persons who cannot obtain insurance through an employer or other group can apply for an individual policy. The individual market includes those who rely on this type of policy as their primary source of coverage, those who use it to supplement coverage not provided in their primary plan, and those who use individual coverage as a bridge between periods of

group coverage. Individual coverage is generally more expensive, and it often provides less coverage than group plans. (Light, 1992)

Small Group. Small group insurance typically includes groups of 25 or fewer individuals though substantially larger groups may be treated as "small" groups. Small groups do not have the advantage of sufficiently large numbers of employees that can share and spread risk of large losses. Consequently, their premium rates rely heavily on the health status of individual members of the group, employee turnover rates, percentage of part-time employees, and employer behavior that affects risk pool stability. Insurers use risk assessment procedures for small groups similar to those used for underwriting individual policies.

The greater uncertainty about potential claims and the expense of administering the policy for a small group lead to higher premiums. The Government Accounting Office reported in 1991 that smaller firms are less likely to offer health benefits due to high cost and low profit levels. The report found that "in 1984, only 46 percent of businesses with fewer than 10 employees offered health coverage. . . . In contrast, almost all businesses with 100 or more employees offered health insurance." (GAO, 1990)

Medium and Large Groups. As the number of employees in a group increases, the likelihood of individual risk assessment decreases. Underwriters select and limit risks by assessing the risk of the group as a whole and either declining to insure the group or tailoring the coverage exclusions to make the risk acceptable to the insurer and affordable for the employer. Underwriters of group health insurance evaluate the risk of the entire group according to age, gender, region, past health care costs, and by the size of the employee pool. These plans frequently restrict benefits for pre-existing conditions. (Light, 1992)

According to the American Academy of Actuaries, large groups, defined as 500 or more members, require less underwriting than individual and smaller group policies.

Unlike some applicants for individual coverage, these groups of insureds are not seeking insurance only when a health need arises. On the contrary, the people in these groups are generally healthy people who are actively at work. A small proportion of them produce a majority of the claims in a year. (Testimony by the Committee on Health, American Academy of Actuaries, 1990) The greater stability of the risk pool in large groups, the greater reliability of risk predictions for large groups, and the ability to spread catastrophic losses among members of a large group reduce the risk of unexpected losses for insurers. (Pokorski, 1992)

D. Community and Experience Rating

Community rating and experience rating are the two primary approaches that have been used by insurers to determine premium rates. Community rating, originally used by most hospital and physician service plans like Blue Cross/Blue Shield, bases the group premium on the average cost of all insured persons within a defined region. By contrast, experience rating bases premium rates on the recent claims experience of the particular group under consideration for coverage. Employee groups are usually healthier on average than geographically defined community groups, which include persons not healthy enough to work. Experience rating also allows insurers to offer lower rates to employers with healthier than average work forces. (Ostrer, et al., 1993) According to the GAO, experience rating became standard procedure for most firms during the 1980s. (GAO, 1990) Commercial insurance firms offer lower rates to groups with better than average risks. The trend toward experience rating of employee groups has resulted in an increased proportion of higher risks in community rated insurance plans, causing premium increases and movement of lower risk groups toward experience rating. As a result, community rated insurance has become less available, and some community rated programs have become insurers of last resort with an increasing burden of higher risk insureds in their pools. (Light, 1992)

E. Health Insurance Underwriting for Individuals and Small Groups

Insurers use a process of risk selection and classification, called underwriting, which evaluates risk factors such as age, gender, occupation, personal and family medical history, hazardous avocations, and use of alcohol, tobacco, or substance abuse. Health insurance underwriters use the insurance application and other sources of information to classify individual risks as standard, substandard, or uninsurable. (Pokorski, 1992) Individuals rated as standard risks obtain insurance with little problem. Those classified as substandard risks can obtain insurance; however, insurers expect these individuals to have higher than average claims. They address substandard risks by charging higher premiums, excluding coverage for specific health conditions, or excluding coverage for pre-existing conditions, either totally or for a defined period. (Light, 1992) Insurers deny coverage to those individuals whose expected claims they judge to be too high to insure profitably. Twenty-five states offer insurance to such individuals through state sponsored pools. These pools are funded in part by premiums of up to 150 or 200 percent of commercial premium levels and subsidized by market share assessments on commercial insurers, but not self-insured employers. (OTA, 1992)

According to the Health Insurance Association of America (HIAA), medical underwriting may be based on some or all of the following sources of information: the "application, agent's statement, medical or paramedical examination, attending physician's statement (APS), hospital medical records, inspection reports, and the files of the Medical Information Bureau (MIB)." (HIAA, 1992)

The Medical Information Bureau (MIB) holds medical information on 15 million individuals in the U.S. and provides it, on request, to member insurance companies. The service has approximately 750 members in the U.S. and Canada. Information is

entered into the MIB data base when individuals apply for health, life or disability insurance. MIB rules prohibit its members from basing underwriting decisions on MIB data, but it is unclear whether this policy can be enforced. (Ostrer, et al., 1993) According to the Office of Technology Assessment, MIB contains information about several genetic diseases and about family diseases. (OTA, 1992)

Inspection reports involve hiring someone to verify application information and to investigate an applicant's "finances, medical history, lifestyle and relationships." (HIAA, 1992) A guidebook for disability insurance sales explains that inspection reports verify application information and investigate the applicant's "habits, moral reputation, business background and motor vehicle record." (Sadler, 1991)

F. Adverse Selection

Insurance underwriters state that adverse selection can occur when applicants have more information than insurance companies about their risk of illness or loss. Underwriters are concerned that when consumers possess information not available to the company, individuals at higher risk may purchase insurance coverage at an unreasonably low premium rate that will not adequately cover loss claims. Such behavior could affect a carrier's solvency if premiums were inadequate to cover losses. Insurers claim that raising premiums for all policy holders to cover such unexpected losses would violate the equity rationale underlying risk classification. Some insurers have argued that such increases could drive individuals at lower risk to obtain cheaper coverage elsewhere or to forego insurance, resulting in a cycle of premium increases to cover the increasing average risk level of the remaining policy holders and drive low risk persons out of the insurance market. Ultimately, this cycle would lead to unaffordable rates. (Pokorski, 1992)

G. Role of Government in Regulation

1. State Insurance Commissioners

Insurance companies, unlike self-insured employers, must comply with states rules and regulations. All states, the District of Columbia, and Puerto Rico have a designated commission, board, or department to issue regulations and rulings and to enforce state insurance laws. The responsibilities of these bodies may include licensing, mandating minimum benefits, overseeing policy renewal and cancellation, approving premium rates, and investigating complaints. Historically the primary purpose of insurance regulation, however, has been to assure insurer solvency. The National Association of Insurance Commissioners provides model legislation on insurance to the States as well as regulatory information to other interested parties. (Ostrer, et al., 1993)

2. Federal Legislation

Although the McCarran-Ferguson Act (1945) gave the states primary responsibility for regulating the insurance industry, several federal laws affect certain insurance practices, including the following:

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) requires that employers continue employees' eligibility for health benefits for a limited period at the employee's expense following conclusion of employment or certain other events that might otherwise disqualify them from eligibility.

The Health Maintenance Organization Act of 1973 established an office in the Department of Health and Human Services to regulate the activities of HMOs and set federal qualification standards including rate setting and underwriting. (OTA, 1988)

3. ERISA and Self-Insured Employers

The Employee Retirement Income Security Act of 1974 (ERISA), which governs employer pension plans, also covers a range of other employer-provided benefits, including health benefit plans. The Act exempts

self-insured employers from state laws and regulations, including mandated minimum benefits, unfair discrimination provisions, and taxes for state high-risk insurance pools. (29 USC 1001-1381)

ERISA also allows employers who self insure to alter or eliminate benefits for specific conditions at any time. A highly publicized court case has focused public attention on this issue. (McGann v. H&H Music, 946 F. 2d 401, 5th Cir., 1991; cert. denied, Greenberg v. H&H Music Company, 61 U.S.L.N. 3352, 1992)

John McGann, who worked for H&H Music, developed AIDS in 1987. Seven months later, H&H Music canceled its commercial insurance plan and began to self-insure. McGann had up to \$1 million dollars worth of lifetime coverage under the original plan. By becoming self-insured, H & H Music was able to retroactively limit his benefits to \$5000, an amount sufficient to cover only a few months worth of medical expenses. Even though Texas state insurance law mandates coverage for AIDS, ERISA's exemption of self-insurers from state insurance laws enabled H&H Music to change drastically the scope of its health care benefits. (Ostrer, et al., 1993)

The Americans with Disabilities Act (42 USC 12101-12213) protects persons with physical or mental impairments, as well as those who may be perceived to have such impairments, from discrimination in employment, public transportation and accommodations, and telecommunications. (Alpers, et al., 1993) Title V of the ADA expressly states that conventional underwriting of risk by commercial insurers or self-insured employers does not constitute prohibited discrimination. The ADA, in keeping with the McCarran Ferguson Act, leaves the regulation of insurance to the states. (Allen and Ostrer, 1993)

4. State Legislation

The states have primary responsibility for regulating the insurance industry. While the exact rules vary by state, state regulation may include:

- licensing requirements, including financial requirements and proof of solvency;
- regulating contracts, particularly individual policies. Providers file insurance forms with the state insurance commissioner to ensure compliance with regulations. The commissioner has authority to disapprove of insurance forms;
- enforcing statutes that prohibit unfair discrimination in underwriting. These statutes cover the issue, continuation, rate classification, and cancellation of policies;
- enforcing mandated benefits, such as coverage of maternity services or drug rehabilitation; and
- taxing premiums. The rate of taxation depends on the type of company. Non-profit plans are not subject to these taxes. (OTA, 1988)

Some commercial insurance laws do not apply to Blue Cross and Blue Shield plans. Instead, the states regulate these plans by legislation that often requires them to follow specific steps in rate setting. (OTA, 1988)

Ten states restrict the use of genetic information and testing for use by insurers. Most of these states' restrictions narrowly apply only to one or two conditions or to carriers of a genetic disorder who remain unaffected by it. (McEwen and Reilly, 1992) Two states broaden restrictions to include all single gene and chromosomal conditions. All of these statutes allow insurers to use genetic information that can be supported by actuarial data or, in some cases, reasonably anticipated experience, except Wisconsin. In 1992 Wisconsin passed a law that prohibits health insurers from requiring or requesting individuals to (1) take a DNA test, (2) reveal whether they have undergone a DNA test, or (3) disclose DNA test results. The bill also prohibits insurers from using DNA test results to determine rates and other aspects of health insurance coverage. (Ostrer, et al., 1993)

5. Influence of market forces.

Market forces may encourage the use of genetic information by insurers. Among these factors are wider use of genetic tests by physicians, consumer awareness and

demand, and competition within the insurance industry. The biotechnology industry and consumer demand may promote the use of genetic testing before the social or scientific implications have been fully considered. Once tests become more widely available to consumers through their physicians, competition within the insurance industry then may encourage the use of this information for insurance purposes.

Biotechnology companies and other commercial interests have recognized the large profit potential of diagnostic tests and have invested in their development. The market for genetic diagnostics in the U.S. could be substantial. Assuming that investors seek to maximize their returns, companies are likely to push for the widespread use of these tests whether or not clinicians and society have established appropriate parameters for their use. (Holtzman, 1989)

Fear of litigation, based on failure to use genetic tests that could have identified a genetic disorder, along with physicians' financial interests in biotechnology companies may increase the use of diagnostic tests. Physicians in clinics that operate a testing laboratory may also tend to promote the use of genetic tests. (Wilfond and Fost, 1992)

In addition to the biotechnology industry's encouragement of clinicians to promote genetic tests, consumer demand also has the potential to influence their use. Consumers may seek testing to make more informed decisions about reproduction as well as their own health care needs. Breast cancer, for example, affects about 175,000 women per year in the U.S., and early diagnosis often leads to better outcomes. If women learn about the existence of a predictive test, there is likely to be widespread demand for it.

Some critics fear that commercialization and advertising of genetic tests will lead individuals to opt for testing without fully considering many of the implications, including the prognostic uncertainty of test results, possible stigmatization, and potential problems with access to insurance and employment. (Billings, et al., 1992) Once the public makes greater use of genetic testing

and the results are found in medical records, competition within the industry may provide insurance companies with the incentive to use genetic information for underwriting purposes. If one insurance company uses genetic tests for underwriting, it could exclude from its pool some applicants who are at greater risk of health costs. Companies using genetic test results in underwriting might thus obtain a competitive advantage over companies that did not consider genetic test results. To maintain competitiveness, other companies would feel pressure to use tests for underwriting. (Murray, 1992) Insurers point out, however, that the incentive to sell policies will inhibit widespread denial of coverage to insurance applicants. (Lowden, 1992)

H. Family perspectives on health care financing.

Family medical history can affect access to insurance both for members of a family who apply for insurance separately and for family members who share a policy. A recent OTA survey of

insurers found that, "personal and family medical histories were the most important factors in determining insurability. . . ." (OTA, 1992) Genetic conditions in family members, whether actual or predicted, have the potential to affect other family members' access to insurance.

members' access to insurance.

The medical problems of one family member can affect other family members covered by the same plan. (Billings, et al., 1992) Many individuals secure health insurance for themselves and their families through their employer. Three in ten people in a national survey reported that a member of their household had experienced "job-lock"—for example, remaining in a job that they otherwise would have left, because a member of the family had developed a medical condition that was covered by their current

employer's plan, but that likely would be excluded from coverage as a pre-existing condition if they were to change employers. (OTA, 1992)

Is genetic risk information special?

Health risk assessments based on information about the presence or absence of genetic mutations have traditionally been limited to the set of health problems classified as "genetic disorders." These disorders have been understood to be caused by versions of specific genes that are inherited from parents and passed on to children. Since relatively few genetic mutations create easily discernible patterns of disease inheritance within a family, the clearest examples of genetic disorders, like Huntington disease, have also been rare diseases. This history still affects the way many people think about genetic risk information in several important ways:

- As the clearest examples of genetic health problems are most predictable within families, genetic risk assessments of any kind are assumed to have more predictive power than other kinds of health risk assessments
- As genetic disorders are perceived as uncommon health problems, caused by internal biology rather than external influences, genetic risk information can be psychologically and socially stigmatizing
- As genetic risks are understood to be heritable, the familial and reproductive implications are often the first consequences considered.

These perceptions continue to make genetic risk an especially sensitive form of health risk information. However, as techniques for detecting genetic mutations improve, the factual basis for these perceptions of genetic risk information is changing. Increasingly, detectable genetic changes are being identified as one among many partially predictive risk factors that can be associated with common, controllable, health problems like diabetes or heart disease. Similarly, mutations in the genes of individual body cells which will not be passed on to the next generation can with greater accuracy be used as indicators of that person's "genetic" risks for specific diseases. In addition, not all genetic information is useful in determining health risks, and most DNA sequences have limited or no utility beyond identification. Our increasing knowledge of the complex interactions between genetic and non-genetic factors in disease makes it increasingly difficult to justify segregating all genetic risk information from other forms of health risk information for policy purposes.

I. Significance of genetic information

Although genetic information is a subset of medical information, it warrants additional attention due to: (1) advances in predictive capabilities; (2) the lack of clear protocols for its use; and (3) the absence of policies to deal with its associated problems.

A number of features characterize genetic information.

Long-range predictive impact. Genetic tests for some disorders or predispositions will be able to predict substantially increased risk of serious health problems long before they are likely to occur, especially late onset conditions, such as Huntington disease, adult onset diabetes, and Alzheimer's disease. (Holtzman, 1989)

Reproductive impact. Genetic test results provide prospective parents with information about current and future pregnancies. This information, in combination with economic constraints and social pressures, can bear on reproductive decision making both before and after conception. (Thomson et al, 1992)

Amniocentesis and chorionic villus sampling (CVS) can detect up to 180 genetic disorders in a developing fetus. Clinicians can perform CVS as early as 10 weeks into a pregnancy, allowing women who discover serious conditions a number of options, ranging from prenatal treatment to early termination of pregnancy.

In addition to prenatal screening, individuals can learn about their potential to pass certain diseases on to their children. Tests for autosomal recessive genes, such as cystic fibrosis, Tay-Sachs, or sickle cell anemia supply adults with information about future offspring before a pregnancy occurs. (Nelkin and Tancredi, 1989)

Race and ethnicity overlap. Certain genetic diseases occur more commonly in specific racial or ethnic groups. Discrimination and stigmatization may not be limited to actual diagnosis of the disease. Positive diagnoses could serve as an excuse for discrimination against individual members of a group. Moreover, all members of a group could face social stigma because of the higher

prevalence of the genetic condition within that group. (OTA, 1992)

Involuntariness and permanence. Genetic conditions are often conditions with which one is born, for which no effective treatment exists, and which remain with the individual throughout his/her lifetime. Unlike some risk factors used in underwriting by insurers (e.g. smoking), genetic conditions are in no sense acquired by voluntary action on the part of the individual.

Familial implications. When genetic information reveals an individual's risk for disease or disability, it also suggests the possibility that family members may be at risk. Genetic testing potentially confronts family members with predictive information that they may not wish to know. In addition to the psychological burdens of anxiety and guilt, such information may also result in discrimination and other social pressures.

Prognostic uncertainty. Predictive tests often provide an individual with probabilities rather than with clear cut information. The uncertainty stems both from the limitations on accuracy of the test and from the type of disease being tested. Although this feature of genetic testing is common to other types of medical testing as well, the lack of predictive certainty in genetic testing may be popularly underestimated.

Diseases may have more than one underlying source. Many of the more common diseases stem from a combination of multiple genes and environmental factors. Identification of one or more genetic mutations associated with a disorder will not necessarily mean that the disorder will become manifest. In some cases the mutation either will not be expressed or the clinical severity of its expression will be limited. Someone may have a gene associated with disease, but may never have symptoms, or at most, experience minor symptoms. Particularly in the case of disorders caused by combinations of more than one gene and environmental factors, clinical manifestation, severity, and age of onset are uncertain. Family studies of neurofibromatosis confirm considerable variation between families as well as extensive variation within families. (Holtzman, 1989)

Stigmatization. Tests that identify "abnormal" genotypes have the potential to single out individuals for differential and discriminatory treatment, based on the myths, fears, and stereotypes of persons who perceive them to be abnormal or to bear a genetic defect. (Billings, et al., 1992; Natowicz, et al., 1992)

Mandatory screening of the African-American population for carriers of the sickle cell anemia genetic trait provides historical evidence of stigmatization based on genotype. Even though carriers of the gene were themselves healthy, they faced discrimination in access to health and life insurance and employment. (Markel, 1992)

A pilot screening program in Greece for sickle cell carriers provides further evidence that information about genetic conditions can shape society's

perceptions. Study participants identified as carriers for sickle cell anemia found that, despite their good health, their marriage options were limited to other individuals who carried the gene. (Hollerbach, 1979)

Family stigma. Unlike other stigmatizing conditions that affect and label only the individual, genetic conditions can stigmatize families as well. Even if no evidence of the condition exists in other family members, they may be stigmatized by their relationship to an individual that has such a condition. The ironic phrase "courtesy stigma" has been used to describe the phenomenon of labelling people related by ancestry to

individuals with stigmatizing conditions. (OTA, 1992)

Psychological/emotional impact of genetic information. Genetic information about individuals and families not only shapes the way others perceive those diagnosed with a genetic condition, it also has a psychological and emotional

impact on the affected individuals and their families. The effects can include psychological trauma from the knowledge that disease is definitely or possibly in one's future. For many diseases, symptoms may not develop for years, if ever, yet the information prompts some individuals to act as though they had the disease. Similarly parents may feel guilty if their children are diagnosed with a hereditary condition. (Wexler, 1992)

Why is genetic counseling important?

Education and counseling are vital components of the genetic testing process. Most genetic tests do not yield results with clear cut implications, and people may find themselves in need of further information and support to cope with the knowledge they gain. Because the results of many genetic tests can be complex, ambiguous or uninformative, the mere uncertainty of a genetic test result may be distressing to people being tested. Moreover, parents of children with genetic disorders may feel especially responsible for their child's genetic condition, and concerned about the implications of the diagnosis for other family members. Sensitive reproductive issues may arise, and pregnant couples may be faced with difficult and painful choices. Talking with a counselor can help to resolve troubling or stressful issues, and allow families to use genetic information in a manner consistent with their own values and beliefs.

The insurance industry has stated a lack of interest in performing genetic tests for underwriting purposes. One of the reasons cited for this is the industry's inability to provide genetic counseling (see the box "What is Underwriting?"). The insurance industry recognizes genetic counseling as an important and inseparable aspect of genetic testing. The counseling component of genetic testing is not covered by many insurance plans. This discourages many persons interested in genetic testing.

Implications for self-perceptions/identity. Assuming that individuals measure their well-being against a standard of "normal human function," disease is a state that limits well-being. Advances in genetic diagnosis make it possible to detect "abnormal" genotypes and label otherwise healthy individuals as sick or impaired. Despite their good health, they may begin to view themselves in those terms, undermining their self-confidence and limiting the plans and commitments they otherwise would make. (Brock, 1992)

Shadow of eugenics. Historically, eugenic policies have promoted the idea that reproduction should be restricted only to those

individuals deemed not to be at risk of passing on hereditary defects, with the aim of "improving" the population. Eugenic theories in the U.S. gained popularity in the early part of this century. Eugenicists tried to explain such conditions as "feeble-mindedness," criminal behavior, drug addiction, and epilepsy. The Eugenics Records Office focused particularly on recent immigrant populations and claimed that they were afflicted by a disproportionately high percentage of these conditions. (Kevles, 1985)

Besides their avid support for restrictive immigration laws, eugenics advocates in the U.S. pushed for the passage of state laws that prohibited or voided marriages between individuals considered to be unfit to reproduce. They also successfully enacted compulsory sterilization laws in some states. Close to 36,000 individuals were sterilized by 1941. Although the sterilizations continued into the 1970s, the eugenics movement lost favor during the 1940s, due in part to public reaction against the Nazi ideology of racial purity and Nazi eugenics programs and in part to growing opposition to these policies among scientists and the public. (Kevles, 1985)

Lack of clear clinical protocols for use. The lack of clear protocols for use of genetic tests, including current uncertainty about potential adverse social consequences, provide further justification for examining genetic information in the insurance context. CF carrier tests offer an example. The OTA's study of carrier screening for cystic fibrosis reveals the absence of agreement on routine carrier screening. Should physicians routinely inform patients about the existence of the test? Should people without a family history of the disease be tested? What are appropriate standards for genetic counselling for CF carriers? According to OTA, critics of widespread carrier testing are concerned about "adequate education and counseling, and prospects for discrimination and stigmatization." (OTA, 1992)

In addition to lacking clear protocols for carrier screening, the professional community has not reached agreement on issues related to testing for p53 mutations (associated with increased cancer risk), even in families with a history of the mutation. On the one hand, early diagnosis has the potential to reduce cancer morbidity and mortality. On the other hand, it has the potential to stigmatize.

As one recommendation concluded:

"An overall benefit of predictive p53 testing cannot be assumed and should be evaluated along with harmful effects in research protocols. Potential psychological, economic and social benefits to those who test negative should be weighed against the increased distress to others who test positive." (Li, 1992)

Currently available laws and regulations do not address adequately the potential to use genetic information in unfair and discriminatory ways. Although the Americans with Disabilities Act is likely to be interpreted to protect against genetic discrimination in employment, transportation, telecommunication, and public accommodations, neither federal nor state statutes currently offer adequate protection against genetic discrimination in health care coverage. (Allen and Ostrer, 1993) Basic reforms are necessary. The recommendations of this Task Force are a useful beginning. More specific plans will have to be developed after the contours of the health care financing reform currently underway have become clear.

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Appendix A

Insurance Task Force Members

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Appendix B

Mission Statement

Background

The purpose of the NIH-DOE Program on the Ethical, Legal, and Social Implications (ELSI) of Human Genome Research is to:

- anticipate and address the implications for individuals and society of mapping and sequencing the human genome;
- stimulate public discussion of the issues
- develop policy options to ensure that the information is used for the benefit of the individual and society.

In pursuit of this mission, the Program's first five year goals are (1) to develop programs of research and public discussion addressed at improving understanding of the ethical, legal, and social implications of the Human Genome Project; (2) to identify and define the major issues and (3) to develop initial policy options to address the highest priority issues. Toward these goals, the Program has established grant-making mechanisms at NIH and DOE designed to support ELSI research and education projects, and a Joint NIH-DOE Working Group on Ethical, Legal, and Social Implications of Human Genome Research to help identify the major issues and develop policy options on the basis of the grantees' work.

Among the high priority issues that the ELSI Working Group has delineated from the Program's initial activities are questions concerning the fair use of genetic information by employers and insurers. Defining the acceptable use of genetic information in determining access to health care financing and life and disability insurance is important because of the significant interests at stake for the parties involved: most notably, individuals and families at genetic risk, private insurance providers, and self-insured employers. Moreover, the challenges that face these parties broaden as

the genetic components of more health problems are uncovered and more DNA-based tests for assessing health risks are developed.

To help define and address the resulting policy issues effectively, the Task Force on Genetic Information and Insurance (Insurance Task Force) has been established by the ELSI Working Group. The Task Force is designed to supplement the ELSI Working Group, by bringing the perspectives of interested parties and experts to bear on its efforts in this high priority area.

Charge

The mission of the Insurance Task Force is to help the NIH-DOE ELSI Program anticipate ethical, legal, and social policy issues raised by the impact of genetic information on the public's access to health care financing, life and disability insurance and to develop suggestions that could be used to forestall potential problems before they occur. To accomplish this mission, the Insurance Task Force will:

1. Gather information on insurance issues from the insurance industry, insurance regulators, consumers, professional groups, ELSI grantees, and other researchers.
2. Facilitate collaboration among ELSI grantees conducting insurance-related research, and serve as a clearinghouse for the products of their research.
3. Identify important new areas for ELSI research related to insurance issues.
4. Develop clear descriptions of current health care financing, life and disability insurance practices relevant to assessing the impact of genetic information on public access to insurance.
5. Develop clear descriptions of emerging advances in genetics and their relevance to insurance practices.

6. Identify and define the primary policy issues raised by genetic information for access to health care financing and life and disability insurance.
7. Develop policy options for addressing the major issues.
8. Report its findings to the NIH-DOE ELSI Program and the ELSI Working Group in a document accessible to policy makers, insurance companies, self-insured corporations, insurance applicants, and other interested parties in May, 1993.

Appendix C

Life and Disability Income Insurance

The Task Force chose to concentrate this report exclusively on genetic information and health care coverage. The focus on health care coverage stems largely from the urgency of the crisis in that sector today. The report does not address specifically life insurance or disability income insurance. Some general comments may be applicable to all three forms of insurance, but, as with all generalities, they must be applied with caution. Adverse selection, for example, is an important factor in all lines of personal insurance. However, its operation, significance and means of avoidance vary with the type of insurance.

Life and disability income insurance have important implications for protecting the confidentiality of genetic information. About half of life insurance coverage is subject to individual risk classification, including medical underwriting.

Life and disability income insurance, no less than health insurance, require examination in the context of burgeoning genetic information. Above all, programs of education are essential, no less for insurers than the general public, if we are to come to grips with new information about our genetic traits, propensities and conditions.

The Task Force does not intend to provide a detailed agenda for further work on genetic information in life and disability insurance. Nonetheless, several questions are worth mentioning:

- **Confidentiality and Privacy.** The routine business of insurance requires some sharing of an individual's personal medical information with third parties. Preserving the

confidentiality of genetic information, despite a very strong industry record on the matter is a concern. Should all redisclosures be made subject to specific informed consent? Can personal identifiers be removed from insurance files in at least some instances of redisclosure? Should physicians be limited to providing only specified information to insurers, rather than continuing the practice of photocopying a patient's entire medical record in response to any insurer's request?

- **A Moratorium on Genetic Tests?** The idea of a moratorium on insurer use of genetic tests for screening applicants has been raised both within insurance circles and among industry observers. What would the implications be of a moratorium? How long might one last? Should it be extended to exclude insurer use of any and all genetic information?

- **A Minimum Policy Available to All?** A new concept has been considered in discussions of insurance and the privacy of genetic information. Some have suggested that while individuals do not have the same urgent need for life insurance as for health insurance, perhaps there is some minimum amount of life insurance that ought to be available to all, as a matter of social equity. Should this coverage be made available with no underwriting at all? Or should some limited underwriting and concomitant increases in premiums be permitted? What level of coverage would meet the test of social justice?

Appendix D

Chronology of Task Force Activities

May 1991

First Meeting of the ELSI Insurance Task Force Cleveland, Ohio

- constructed a plan of action for developing guidelines by 1993
- set a time frame for future meetings

December 1991

Second Meeting of the ELSI Insurance Task Force, Washington, DC

- briefed on the use of genetic data by insurance companies
- briefed on technical prospects for future genetic testing
- created a subcommittee to analyze cases of genetic discrimination assigned information gathering tasks to members

Invited Consultants:

John Cova, Ph.D., and Tony Hammond, Health Insurance Association of America; Katherine Klinger, Ph.D., Integrated Genetics, Inc.; Reed Pyeritz, M.D., Johns Hopkins University; Sandy Lowden, M.D., Crown Life Insurance; Warren Schrier, Benefit Trust Life.

March 1992

Third Meeting of the ELSI Insurance Task Force, Bethesda, MD

- briefed on legislative and regulatory issues concerning genetic testing and insurance, including self insured companies
- drafted set of core principals for further discussion and refinement

Invited consultants:

Mary Ann Bobinski, J.D., University of Houston Law Center; Deborah Chollet, Georgia State University; Peter Groom, California Department of Insurance; Sandy Lowden, M.D., Crown Life Insurance; James Hanson, U. of Iowa.

Background papers:

Jude Payne. "The Health Insurance Implications of Genetic Testing" March 1992.

Phillip Reilly. "Policy Positions on Genetic Testing and Discrimination" March 1992. and James Hanson. "Previous Studies and Commissions Examining the Relationship of Genetic Services to Insurance and/or Genetic Discrimination," March 1992.

Interim report:

The interim report of the ELSI Insurance Task Force. April 1992 (Human Genome News 4(1): May 1992.)

May 1992

Fourth Meeting of the ELSI Insurance Task Force, Bethesda, MD

Accomplishments:

- drafted outline of final report
- assigned subgroups to gather information on adverse selection and the flow of genetic information between genetic tests, medical records, and insurance companies

Invited consultant:

Sandy Lowden, M.D., Crown Life Insurance.

Background papers:

Betsy Anderson, Jonathan Beckwith, and Rob Bier. "A Definition of Genetic Testing" June 1992.

Interim report:

Insurance Task Force meeting report. Human Genome News 4(3): September 1992.

November 1992

Fifth Meeting of the ELSI Insurance Task Force, San Francisco, CA

Accomplishments:

- Developed and refined consensus statements
- Defined open policy issues and developed policy options.
- Drafted letter to President-Elect Clinton

Background papers:

Vicky Laden and Paul Billings. "Greenberg v. H & H Music Company" November 1992.

Betsy Anderson. "The Flow of Genetic Information" November 1992. (packet)

Sandy Lowden. "Principles of Underwriting" September 1992.

Interim reports:

Letter sent to President Clinton, January 1993

February 1993

Sixth Meeting of the ELSI Insurance Task Force, Crystal City, VA

Accomplishments:

- Refined open policy issues and policy options.
- Reviewed draft background section of final report.

March 1993

Seventh Meeting of the ELSI Insurance Task Force, Bethesda, MD

Accomplishments:

- Finalized recommendations
- Finalized plans for distribution

Background paper:

Paul Billings. "The Study of Genetic Discrimination: A Case-based Investigation" March 1993.