It is a great honor to meet with you during the opening session of the world’s first International Underwriting Congress. I was asked by the program committee to discuss “Medical Underwriting in the Genetic Era.” This topic is a fitting introduction to this week’s discussion of issues of global importance to underwriting professionals. I believe concerns engendered by genetic testing represent the most serious threat to risk classification that we will experience in our working careers. In brief, the issue is as follows. The field of genetics is experiencing exponential growth, with a corresponding recognition that most medical information, screening and diagnostic tests, and disease processes have a genetic component. These scientific advances have been accompanied by fears that insurers will misuse genetic information to the detriment of the general public. Accordingly, a number of countries have proposed and/or enacted legislation to restrict insurers’ access to and/or use of genetic tests and genetic data, legislation that would, in some cases, prevent access to information that is essential for classifying medical risks.

My remarks will focus on the most critical insurance issues: redefining medical information in genetic terms, antiselection, discrimination, definition of genetic tests, genetic testing legislation, likely resolution of this debate, and steps we can take to protect risk classification. A more comprehensive analysis of this subject has been distributed to the audience in the form of a reprint from the January 1997 issue of the American Journal of Human Genetics.

Redefining Medical Information in Genetic Terms
Medical practice is entering an era in which it will be difficult if not impossible to draw meaningful distinctions between genetic and nongenetic information. In their comprehensive analysis of disorders with a genetic component, the authors of The Genetic Basis of Common Diseases listed virtually all of the conditions encountered in an average medical practice. Overlap between genetic and nongenetic information has been acknowledged by the National Center for Human Genome Research which observed that “For policy purposes, it will become increasingly difficult to distinguish genetic from nongenetic diseases, and genetic information from nongenetic information.” The lack of a clear boundary between genetic and nongenetic conditions and tests was also recognized by the American Society of Human
Genetics Ad Hoc Committee On Insurance Issues in Genetic Testing, and in an editorial in the British journal Lancet which opined that "it will soon be impossible to talk of medical and genetic tests as separate creatures." Genetic experts even envision the time when the public will be offered genetic screening via "walk-in testing (e.g., at shopping malls), mail-order kits, and home test kits ..." These latter predictions seem futuristic, but in Britain it is now possible to purchase cystic fibrosis test kits by mail without consulting a physician. An oral fluid sample containing cells from the mouth is collected by the individual, sent to the testing laboratory, and results are received via the mail.

These official pronouncements that genetic and nongenetic information will often be indistinguishable make it clear that much of the data now used in day-to-day underwriting is being redefined in genetic terms. The scope of this "geneticization" of medical information includes routine underwriting parameters such as family history, serum cholesterol and blood glucose, physical examinations, and virtually all common medical impairments. Insurers are facing the scientific reality that most medical tests, diseases, and data will have a genetic component, while at the same time being confronted with legislation that seeks to prohibit use of all genetic information during risk classification. Against this backdrop of unparalleled changes in medical practice and onerous legislation lies a fundamental business principle: in order to sell individually underwritten insurance, where premiums are based on an applicant's claim risk relative to other people of the same age and gender, insurers need access to the same information - genetic or nongenetic - that is known to their applicants.

Antiselection

The purpose of risk classification is to group risks with similar characteristics in order to establish an equitable price for each risk group. This goal cannot be achieved unless both the applicant and the insurance company have the same level of knowledge about the magnitude of the risk. Any system which, by design or Government intervention, permits the applicant to have superior knowledge will inevitably lead to antiselection.

Historically, antiselection via use of genetic information has not been a serious problem, with both insurers and applicants operating on what might be characterized as "mutual genetic ignorance." This situation has changed. During the next decade, hundreds of thousands of genetic tests will be performed, primarily on people at high risk of disease. Individuals will have access to information indicating they are at significant risk of a serious disorder or are already in the presymptomatic phase of a disease process. Many of these people will alter previous buying practices, i.e., choose to buy insurance when they would not have done so absent an unfavorable test and, most importantly, fail to inform the company of the results at the time of application. The medical literature has already reported instances where high risk individuals have "attempted to buy life insurance or increase the amount of their coverage when they first learned of their at-risk status or when symptoms of the disease appeared." The impact of antiselection will be greater than predicted by the number of people involved since it is likely these individuals will (1) buy more insurance than average policyholders, (2) submit claims much earlier than expected, and (3) selectively purchase coverage, e.g., buy life insurance if early death is likely, disability income or long term care insurance if the disorder is disabling but not life-threatening, and critical illness insurance if a lump sum cash benefit is desired at the time of diagnosis. Antiselection is especially worrisome with products where the benefit is paid directly to the policyholder rather than a beneficiary. For example, if applicants at risk of hereditary cancer (or other conditions covered by the contract) have the right to conceal test results, insurers
who sell critical illness coverage are contractually obligated to pay a lump sum (potentially in amounts of $500,000 or more) at the time cancer is diagnosed even though the malignancy may be detected at an early stage and cured.

Those opposed to sharing genetic information with insurers argue that antiselection will be a rare event, that its impact will be diluted when spread among all insurers, or that it must be tolerated regardless of its magnitude in order to guarantee coverage for everyone. These comments display a lack of appreciation of the staggering financial advantage that can be attained when one party in a contractual agreement knows more than the other. Some people will attempt to use genetic test results to create an estate when none would have existed prior to testing. Suppose a 30-year-old man decides to buy life insurance after learning via a genetic test that he is likely to die within 5, 10, or even 20 years, a life expectancy similar to that of a man aged 89 years, 79 years, or 62 years, respectively. Realizing that higher premiums were likely, the applicant might (1) purchase life insurance at standard rates if he could conceal the test result, or (2) invest the money he would have spent on premiums. A $100,000 10-year level term life policy can be purchased for as little as $125 per year, and a 20-year level term policy for $151 per year, and the insurer is obligated to pay $100,000 in the event of death. In comparison, the same annual premiums invested at 10% per year would yield a return of $2191 after 10 years ($125 invested annually for 10 years), or $9513 after 20 years ($151 invested annually for 20 years). For many people, the temptation to buy insurance under these circumstances will be irresistible. Simply stated, if life expectancy is much shorter than anticipated, purchasing life insurance at standard rates is the world’s best financial investment.

Discrimination
A recurring criticism is that unfavorable genetic information will be used by insurers to rate (charge higher premiums) or decline new applicants, as well as deny claims on in force business on the grounds that unfavorable genetic characteristics constitute a preexisting condition. Critics charge this eventuality would result in genetic discrimination and creation of a “genetic underclass” who would be unable to afford or obtain insurance, and only persons with favorable genetic characteristics would be able to buy coverage at affordable rates.

The premise that use of significant medical information to classify risks constitutes a discriminatory practice strikes at the very heart of the private insurance business. Discrimination based on race, ethnicity, and religion is vilified as an affront to the mores of all societies that subscribe to egalitarian principles, and use of these factors by insurers is generally prohibited. Yet most countries have codified into law statutes that explicitly allow discrimination via other risk parameters (exempting race, ethnicity, and religion) within the context of private insurance, with the proviso that such discrimination is based on factors that exhibit a strong correlation with the risk accepted by the insurer. Underpinning this apparent paradox is acknowledgment by legal and regulatory authorities worldwide that, in a private, voluntary insurance market where applicants decide if they want to buy insurance and then choose the type, timing (when it’s purchased), and amount of coverage, insurance cannot be sold without basing premiums on the risk - genetic or nongenetic - presented to the insurer.

In the United States, the question of what constitutes acceptable ("fair") vs. unacceptable ("unfair") discrimination in the context of insurance is governed by unfair trade practices acts which prohibit unfair discrimination. The first Model Unfair Trade Practices Act...
for insurance was adopted by the National Association of Insurance Commissioners (NAIC) in 1947. An unfair trade practice is defined in Section 4G(1) of the Model act as: "Making or permitting any unfair discrimination between individuals of the same class and equal expectation of life in the rates charged for any life insurance policy or annuity or in the dividends or other benefits payable thereon, or in any other of the terms and conditions of the policy." There is no question that laws based on this Model act permit fair discrimination, as well as prohibit unfair discrimination. All States and the District of Columbia have now enacted the Model act or substantially similar legislation.

There is a more compelling reason why insurers must use genetic information: consumers buying individually underwritten insurance will continue to demand that we base underwriting decisions on an applicant's risk relative to others of the same age and gender. In my experience, some of the strongest proponents of risk classification based on genetic factors have been people with milder forms of genetic disorders such as Gaucher's disease, cystic fibrosis, and alpha-1 antitrypsin deficiency. They have refused to be classified with applicants having more severe manifestations of the same diseases and insisted that insurance premiums reflect their more favorable risk status. In the future, these applicants will assuredly be joined by (1) individuals whose genetic mutations are less serious, (2) those with negative genetic tests, (3) people with genetic characteristics that confer health and/or survival advantages, and (4) applicants whose risk of genetic disease is markedly reduced by proper medical care, e.g., patients with the HNPCC genotype (hereditary nonpolyposis colorectal cancer) who have regular surveillance for prevention or early detection of cancer will demand cheaper insurance premiums. Suggesting that insurers selectively use genetic information, i.e., credit favorable genetic factors and disregard all unfavorable data, is unrealistic and represents a serious impediment to resolution of this issue. No private enterprise would be willing to operate in a business environment where downside risks were ignored and prices were quoted based on a best case scenario.

The principle of insurance discrimination was conceded more than 100 years ago; it operates countless times each day when insurers charge premiums that reflect the likelihood of a claim. Ultimately, objections to use of genetic information will be subsumed by economic and scientific realities: individually underwritten insurance cannot be sold without risk classification and much of the medical information needed to classify risks will be genetic. This eventuality has been recognized in an editorial column in the journal Nature which opined that "in the end, both insurer and policyholder will have to share [genetic] information equitably - there is no long-term alternative to consensual discrimination."12

Definition of Genetic Tests
Of paramount importance to insurers is the meaning of "genetic test." If a broad definition is used in laws or regulations that restrict insurers' access to genetic data, companies would be severely limited in their ability to classify risks. For example, the definition provided by the Task Force on Genetic Testing of the NIH-DOE (National Institutes of Health-Department of Energy) Working Group on Ethical, Legal and Social Implications of Human Genome Research reads as follows: "Genetic tests- The analysis of human DNA, RNA, chromosomes, proteins or other gene products to determine the presence of disease-related genotypes, mutations, phenotypes or karyotypes for clinical purposes. Such purposes include prediction of disease risks, identification of carriers, monitoring, diagnosis or prognosis, but do not include tests conducted purely for research."13 This definition illustrates problems that broad language can create for insur-
ers: (1) it covers the full spectrum of disease ranging from asymptomatic carrier status to symptomatic illness, (2) tests for proteins or other gene products are included, and (3) use of genetic tests is limited to clinical purposes. Legislation based on this definition would effectively prevent insurers from classifying risks even if symptoms had already developed, and use of routine tests such as serum cholesterol and blood glucose would be prohibited because these tests could be considered gene products.

In response to efforts by state legislatures to regulate use of genetic data by companies selling medical expense coverage, the following definition has been used in various forms by United States insurers in an attempt to limit the impact of this legislation: "Genetic test means a laboratory test of human DNA or chromosomes from an individual which is (i) used to identify the presence or absence of inherited alterations in genetic material which are associated with disease or illness, including carrier status; and (ii) a direct measure of the presence or absence of such alterations. The term genetic test does not include a test of indirect manifestations of any such alterations. This definition is quite specific on several points: it is limited to laboratory tests of human DNA or chromosomes; it covers tests that identify the presence or absence of inherited alterations in genetic material, but does not include non-inherited diseases in which the genetic alteration is caused by external factors such as cigarette smoke, ultraviolet light, or environmental toxins; and the definition refers only to direct measures of the alterations and expressly excludes tests of indirect manifestations of genetic alterations (gene products) such as serum cholesterol and blood glucose.

Several caveats are noteworthy regarding definitions that may be incorporated into laws or regulations. First, the context in which the definition is used is as important as the definition itself. The foregoing industry definition would be acceptable for certain purposes, such as reasonable informed consent or confidentiality requirements. On the other hand, the same definition would not be acceptable if it were used to prohibit use of genetic test results during the underwriting process, the reason being that the definition includes the types of genetic tests that will become routine medical practice in the future, and insurance companies would be at a marked disadvantage if they were unable to access important risk information known to their applicants. Second, experience has shown it is almost impossible to predict how the definition of "genetic test" will evolve during the legislative process. For example, if insurers were willing to agree to restrictions on use of genetic information based on a certain definition, the definition might be changed later in the legislative process in response to pressure from special interest groups, thereby making the proposed law totally unacceptable. Finally, the issue of an acceptable definition is a fluid situation that requires constant reassessment. Seemingly harmless laws passed in 1997 might have catastrophic effects on insurers as researchers discover that genetic factors are a near-universal component of screening and diagnostic tests, and most or all nontraumatic impairments.

The concern of insurers extends beyond the definition of a genetic test. Equally problematic are references to "genetic information," "genetic disease," and "genetic characteristics." For instance, legislation filed (but not enacted) in 1996 in Connecticut would have prohibited underwriting for health or disability income insurance on the basis of "information about genes, gene products or inherited characteristics that may derive from an individual or family member." This language could be interpreted to include height, weight, serum cholesterol, or even disease processes that were already symptomatic.
Genetic Testing Legislation

Use of genetic information in the context of private insurance is being discussed at some level in all countries with mature insurance markets. In some cases, discussions have been confined to medical societies and scientific publications. Other countries have elevated this topic to Governmental committees, and/or proposed or enacted laws restricting insurers' access to and/or use of genetic data. Medical expense coverage is generally the initial focus of the debate because most people think this type of insurance is a right, i.e., everyone is entitled to medical expense coverage by virtue of citizenship. Subsequent discussions invariably concern life, disability income, long term care, and critical illness insurance even though these latter types of coverage are widely viewed as financial products. To the best of my knowledge, genetic testing legislation has been enacted only in the United States and Europe.

United States

In the United States, proposed legislation to restrict insurers' use of genetic information has focused primarily on health insurance. The driving force behind these efforts has been the unique status of this type of coverage in the U.S. In contrast to countries with National health insurance programs, private health insurance is generally needed to access the health care delivery system in the United States. Supporters of genetic testing legislation were concerned that it might be difficult to obtain health insurance if companies were allowed to underwrite using genetic factors. (From a regulatory perspective, health insurance typically includes medical expense, disability income, long term care, and critical illness insurance, plus supplemental medical expense coverage. However, laws dealing with health insurers' use of genetic information generally target medical expense coverage).

Legislative efforts to restrict use of genetic information closely paralleled advances in genetics and further accelerated after publication of a 1993 report by the National Institutes of Health (NIH) which concluded that genetic information should not be used to deny health care coverage. Despite an explicit statement in the NIH report that their recommendations “concern health care coverage and should not be applied uncritically to other forms of insurance, such as life or disability income insurance,” subsequent draft legislation concerning insurers' use of genetic information often included not only health insurance but also life and disability income coverage.

In 1989 only one bill dealing with use of genetic information by insurers was proposed in the 50 states. By 1993 approximately 15 state bills were introduced, and by 1996 the number grew to at least 28 bills in 15 states. However, state laws enacted to date reflect the perception that issues involving health insurance are fundamentally different from those concerning life and disability income covers, as well as the industry's successful efforts to protect life and disability income underwriting. Fifteen states have passed laws addressing use of genetic information in the context of health insurance, but no state has prohibited or restricted use of genetic data when underwriting life or disability income insurance, with the exception of Colorado which prohibits underwriting based on genetic factors for group disability income insurance. Regarding Federal legislation, Congress recently passed the Kassebaum/Kennedy Health Insurance Portability and Accountability Act of 1996. This law provides that genetic information, in the absence of a diagnosis of the condition related to such information, shall not be a pre-existing condition under group health insurance. It also prohibits use of genetic information as well as health status, medical condition and medical history, among other things, in considering eligibility for group health insurance. Eight additional bills concerning genetic testing were pending in Congress in
1996; five dealt almost exclusively with health insurance. It is expected that as many as six genetic privacy bills will be introduced at the Federal level in 1997, the most important of which will probably be a redrafted version of a bill introduced last year by Senator Pete Domenici entitled the “Genetic Confidentiality and Nondiscrimination Act of 1996.” This legislation would prohibit unfair use of genetic information by employers and health insurers.

Europe
The situation in Europe with respect to laws governing use of genetic information is more complicated because three entities must be considered: the European Union, the Council of Europe, and legislation in individual European countries.

European Union
On March 16, 1989, the European Parliament adopted a Resolution on the Ethical and Legal Problems of Genetic Engineering. This Resolution had no legal authority in the member States of the then European Community but it sensitized people to problems that might arise in the future. Principle 19 states that “Insurance companies have no right to demand that genetic testing be carried out before or after the conclusion of an insurance contract nor to demand to be informed of the results of any such tests which have already been carried out and that genetic analysis should not be made a requirement for the conclusion of an insurance contract.” Principle 20 indicates that “The insurer has no right to be notified by the policyholder of all the genetic data known to the latter.” It is not clear whether these Principles address private insurance as a whole or only private medical expense insurance.

An accompanying explanatory report states that “It has not been usual in the past to categorize insurance risks on the basis of hereditary factors and this must remain the case in future,” and “Whilst, in an insurance contract, the contracting parties must have the same information with regard to the probability of the event insured against, the insurer cannot claim any right to protection in respect of estimates concerning possible risks, risks which may [manifest themselves] in the distant future or the identification of predispositions which will only be activated under certain environmental conditions.”

Council of Europe
The Council of Europe is an inter-governmental organization comprised of forty European countries. Among the goals of this organization is development of legislative solutions to social problems facing member States, e.g., minority rights, AIDS, bioethics, and protecting the environment.

In 1992, the Committee of Ministers of the Council of Europe adopted Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes. Principle 7 stipulates that “Insurers should not have the right to require genetic testing or to inquire about results of previously performed tests, as a pre-condition for the conclusion or modification of an insurance contract.” With the exception of the Netherlands, all members of the Council of Europe adopted this Recommendation.

The Council of Europe released a draft Bioethics Convention in 1994, which was later modified and finally rewritten. A final version was published November 19, 1996 entitled “Convention For The Protection Of Human Rights And Dignity Of The Human Being With Regard To The Application Of Biology And Medicine: Convention Of Human Rights And Biomedicine.” Article 11 (Non-discrimination) states that “Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.” Article 12 (Predictive genetic tests) stipulates that “Tests which are predictive of genetic diseases or which serve either to iden-
tify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.” This Convention is open for signature by member States of the Council of Europe, non-member States, and the European Community, and it will become effective if signed by five States (four of whom must be members of the Council of Europe). Thereafter, States choosing to sign the Convention would be required to transpose all articles into National law, excepting specific provisions that conflicted with existing law.

**Individual European Countries**

Belgium- Articles 5 and 95, respectively, of legislation enacted in 1992 stipulate that applicants cannot transmit genetic data to insurance companies, and physicians cannot transmit the results of “genetic analysis techniques” capable of determining future state of health.

France- Laws No. 94-653 and No. 94-654 (1994), respectively, limit use of genetic information to medical and research purposes, and impose a penalty of one year’s imprisonment and a fine of FRF 100,000 (Art. 226-26 of the Penal Code) if information about genetic characteristics is used outside a medical or research setting. Coincident with discussion of these laws, the French Federation of Insurance Companies announced a moratorium on use of genetic information - favorable or unfavorable - during the underwriting process. Both the laws and the moratorium expire after 5 years.

Austria- A law dated July 12, 1994 states that insurers cannot obtain, request or use results of genetic analysis.

Norway- Law No. 56 (August 1994) indicates that genetic tests can be performed only for medical diagnostic and/or therapeutic purposes (Chapter 6-2), and stipulates that third parties (e.g., insurers) cannot request, receive, retain, or make use of genetic test information (Chapter 6-7).

The Netherlands- There is an indefinite moratorium on insurers ordering or using genetic information for policies below NLG 300,000.

Sweden and Denmark- Each country has proposed legislation to limit insurers’ access to genetic information but no laws have been enacted.

United Kingdom- The House of Commons and the Government have disagreed on whether or not there is need for legislation to limit use of genetic information by insurance companies. In July 1995, the House of Commons Select Committee on Science and Technology proposed creation of a Human Genetics Commission to regulate medical uses of genetics and provide advice on issues including use of genetic information for insurance purposes. The Committee also criticized the insurance industry for failing to propose a solution for dealing with genetic data. In response to these recommendations, the Government stated that a Human Genetics Commission was not necessary, and there was no current or foreseeable need to enact legislation to regulate use of genetic information. The Government also stated that the attitude of the insurance industry had been appropriate, and they encouraged dialogue between the Association of British Insurers and leading geneticists in the hopes of creating an industry-wide code of practice that would address how genetic information should be used by insurers. Subsequently, the British Government announced it would create a National commission that would function in an advisory capacity (but have no regulatory powers) to review genetic developments that might affect public health, employment, and insurance.
An important development occurred on October 7, 1996 when the Association of British Insurers announced that Professor Sandy Raeburn of the University of Nottingham had agreed to become its part-time genetic adviser. According to the ABI, Professor Raeburn will assist the Association in keeping up to date on genetic developments and in drawing up a Code of Practice for handling genetic information. He will also work closely with Consultant Medical Officers and other industry experts on the subject. As a further indication of its commitment that insurers will handle genetic information with great sensitivity and confidentiality, the ABI has extended an invitation to the British Society for Human Genetics to join with them to review current and future arrangements with respect to dealing with genetic data.

On February 18, 1997, the ABI issued an updated Policy Statement on Life Insurance and Genetic Testing. The statement applied to life insurance only, and not to medical or health insurance sold separately or with life insurance. Four items were noteworthy. First, companies will not require anyone to take genetic tests when applying for coverage. Second, unless indicated otherwise by the insurance company, applicants should report results of any genetic tests completed prior to the application. Third, special provisions apply to applicants for life insurance when coverage is directly linked to a new mortgage for a private dwelling: "Any genetic tests which are to the detriment of applicants for life insurance up to a total of £100,000 will be ignored when the insurance is linked to a new mortgage for a home. Life insurers are able to provide this assurance [insurance] for what has been identified as an especially sensitive area because the risk of selection [antiselection] against them is somewhat less than for policies issued in other circumstances." Family history and other medical information will still be used during the underwriting process. Fourth, for other (non-mortgage) life insurance applications, individual companies will decide whether or not they wish to consider the results of previous genetic tests.

**Summary of Legislation in Europe**

A central theme of European legislation is the desire to find a permanent solution to the question of "How should genetic information be used by private insurance companies?" Most of the enacted legislation conveys the impression that there is a simple solution to this extraordinarily complicated problem, namely, simply prohibit use of all genetic information by insurers. Among the shortcomings of legislative efforts to date are the following:

1. Insufficient understanding of the private insurance business, particularly, (1) the difference between products that are individually underwritten vs. those issued in a group context, and (2) the fundamental difference in these issues for medical expense coverage as opposed to life, disability income, long term care, and critical illness insurance.

2. Failure to acknowledge that insurers worldwide practice legally-sanctioned discrimination countless times each day. With respect to genetics, medical underwriters have used genetic factors since the foundation of the modern insurance industry more than one hundred years ago, e.g., family history, height and weight, blood pressure, serum cholesterol and blood glucose levels, and history of disorders such as coronary heart disease, diabetes mellitus, Huntington's disease, cystic fibrosis, and polycystic kidney disease.

3. Absence of definitions for genetic test, genetic information, and genetic disease.

4. Failure to recognize two critical distinctions between genetic tests: (1) genetic tests that identify a predisposition (an event which may occur) vs. tests used to make a diagnosis (an event which has already occurred), and
likely the tests for inherited disorders vs. tests based on genetic technology and used in the context of nonhereditary conditions.

5. For legislation based on models developed by the European Union and the Council of Europe, lack of appreciation of the deleterious effects of legislation written by a single entity on diverse insurance markets. In a free market economy such as the European Union, legal or regulatory constraints that increase the cost of insurance in one country will induce healthy people to purchase cheaper coverage in another market, as well as encourage individuals at higher claim risk to buy insurance in countries with lower prices.

In my opinion, European legislation will be modified in the future. Underlying legislative reform will be the realization that individually underwritten insurance cannot be sold without risk classification and much of the medical information needed to classify risks will be genetic.

Likely Resolution of this Debate
Genetic issues discussed in this paper are being driven by the research and medical communities, with private insurers following their lead. It is unreasonable to expect that underwriting practices could be frozen in the 20th century amid a sea change in medical practice and consumer understanding. Without information needed to estimate risk there can be no risk classification, and without risk classification there can be no individually underwritten insurance. This absolute dependence on predictive data is the reason insurers react so negatively to suggestions that they not use genetic information. The issue is not “will premiums increase a little or a lot;” rather, it is that prohibiting use of predictive information - genetic or nongenetic - represents a frontal assault on a fundamental business practice.

I believe an organized effort could succeed in limiting insurers’ access to genetic data. It might even be possible to achieve the “holy grail” of some critics: legal prohibition of use of genetic information during the underwriting process. At best, this eventuality would result in price increases that place insurance beyond the reach of many people, particularly those already least able to afford coverage; at worst, it could threaten the financial solvency of the industry. But these issues will not be resolved by legislative fiat or organized efforts within the medical community to restrict access to information. They will be decided by consumers. In the end, people will “vote with their feet,” i.e., they will choose a solution that most closely meets their needs. As viewed from the perspective of a physician, medical director, and insurance consumer, the solution will almost certainly entail total acceptance of the use of genetic factors in risk classification. The explanation lies in the economic imperative: there is no viable alternative to the private insurance mechanism. If the populace decides to endorse a system that calls for significantly higher premiums in order to subsidize others at greater risk, that is their right. For most people, however, willingness to subsidize others will quickly fade with the realization that, even if they are willing to “play by the rules” and purchase insurance “blinded” to their genetic status, many others will not be so forthright, and the latter will use genetic information as the basis for choosing the type, amount and timing of insurance purchases. Confidence in such a system will further erode when consumers realize that genetic tests, diseases and information have become sacrosanct, and insurance premiums are no longer determined by one’s claim risk relative to other policyholders of the same age, but according to whether or not a test result, diagnosis, or risk factor has a genetic component (e.g., if there were an increased but virtually identical likelihood of early claim in two 40-year-old applicants, and the risk was genetic in one person and nongenetic in the other, prohibiting use of genetic information would mean that only the individual with nongenet-
A Lancet editorial asks if society might be willing to restrict genetic information to direct medical uses and "forgo any premium advantage in being able to show that we are genetically at low risk." Though laudable, this proposal has no chance of success. For those questioning the assertion that people are unwilling to subsidize others at higher risk, imagine that an insurer would agree to accept everyone at risk of a serious disease with the stipulation that (1) the premium would be the same for everyone regardless of risk, and (2) genetic test results - favorable or unfavorable - could not be used to either increase or decrease the premium. Such a plan would be welcomed by those with an unfavorable test but those with a favorable result would never accede to such an arrangement. This contention is supported by a consumer survey conducted by the American Council of Life Insurance. Existing policyholders were asked if they would be willing to pay more for life insurance so that everyone could receive coverage at the same rate, regardless of the risk they represented to the company. Twenty-seven percent would pay more; most people in this group wanted increases limited to 10% or less. Overall, only 2% of policyholders were willing to increase their premiums by as much as 11% to 25% to ensure that rates were the same for everyone.

Admittedly, the immediate future will be a difficult period for insurers since testing will almost exclusively target people at high risk of genetic disease, and any circumstance requiring an extra premium will be trumpeted by the medical and lay press as proof that insurers practice genetic discrimination. This unfavorable press will fade when testing spreads to the general population. Genetic testing will be readily available in doctors' offices, free-standing commercial laboratories, and eventually, via home testing, and people will learn that risk conferred by genetic characteristics spans a range from low to high, with most individuals having an average risk. If confronted with de facto forced subsidization by regulations or professional codes of conduct that forbid sharing of information except when it confers a financial advantage, applicants who know they have neutral or favorable genetic profiles will insist that insurers use this information to grant lower premiums. Consumer purchasing decisions are not governed by utopian precepts, but by rules established in perpetuity, namely, to maximize personal financial gain.

Steps to Protect Risk Classification
I will conclude my remarks by suggesting a number of steps we can take to protect risk classification.

First, I believe each insurance market should immediately form a Genetic Testing Task Force to proactively deal with these issues. Comprising this Task Force would be specialists in legislative matters, underwriters, medical directors, actuaries, and other insurance professionals. It is worth emphasizing that this debate will be won or lost in the legislative arena. Insurers cannot hope to prevail simply by arguing they have a historic right to underwrite.

Second, establish parallel tracts for discussion of medical expense insurance, and all other forms of insurance. This arrangement is a recognition of the fact that most people believe medical expense coverage is a right that should not be jeopardized by use of genetic information, as well as an acknowledgment that individually underwritten forms of life, disability income, long term care, and critical illness insurance cannot be sold unless companies have access to the same medical information - genetic and non-genetic - that is known to their applicants.

Third, analyze insurance needs of individuals who may have difficulty obtaining coverage with a goal of developing new insurance...
products that provide the necessary protection while safeguarding the company and other policyholders. This topic is embryonic in its development and possible solutions abound. An initial step might be an organized campaign by physicians, genetic counselors, and insurers to stress maximum participation in insurance coverage that is sold on a group basis, and to encourage purchase of individually underwritten insurance several decades before the likely onset of disease. From a product perspective, endowment life insurance has great potential; when purchased at a young age, this product may satisfy the insurance needs of most individuals at high but predictable risk of a serious genetic disease. Another possibility is decreasing term or limited term (e.g., 10- or 20-year) life insurance. Other product design features might follow a recommendation made by Ostrer et al. who noted that “insurers may offer a standard risk classification to persons who engage in healthy behaviors shown to mitigate the higher risk of their genetic predisposition to disease, especially if compliance can be monitored.”

Fourth, establish a dialogue with organizations that will play a pivotal role in resolving these issues. For example, medical societies generally have great influence on the opinions of consumers, legislators, and their physician members. It would be very beneficial to hold a series of meetings with physician groups to explain our concerns regarding antiselection, individually underwritten vs. group coverage, and differences between medical expense coverage as opposed to life, disability income, long term care, and critical illness insurance.

Finally, we must remember that the business of private insurance has thrived because our industry provides a mechanism to supplement social benefits granted by the State. Given the inability of Governments to fund all of the programs desired by the populous, there is reason to believe the role of private insurance may increase significantly in years to come. However, if the insurance industry wants society to afford it a greater social role, it must accept the increased social obligations which that entails. With regard to genetics, this means insurers must find a way to integrate genetic information into risk classification while still maintaining or even increasing the percentage of people who are able to purchase coverage. The alternative is to accept a more limited role in which private insurance practices will be of less concern for social policy.

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