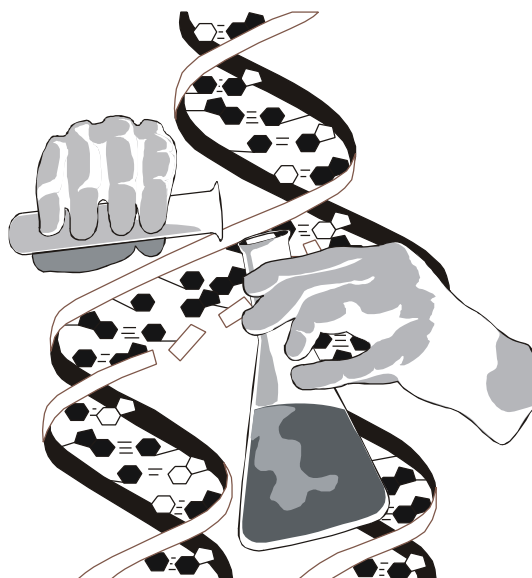


GENETIC TESTING IN HEALTH, LIFE, AND DISABILITY INSURANCE IN KENTUCKY

(SENATE RESOLUTION 161)



**Prepared by:
Laura H. Hendrix
LRC Staff**

Research Report No. 289

*Legislative Research Commission
Frankfort, Kentucky*

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FOREWORD

Senate Resolution 161, 1998 Regular Session of the General Assembly, mandated a study of the impact of genetic testing on health, life, and disability insurance. This research report provides an assessment of the impact of genetic testing on insurance in Kentucky, in the context of Kentucky, federal, and other states' legislation. The report examines the evolving science of genetics, the competing interests at issue in genetic testing and insurance, and laws and regulations regarding genetic testing and insurance. The report also presents the results of a survey of selected insurance companies. Additionally, experts on genetic testing were consulted for their input.

The report was prepared by Laura H. Hendrix of the LRC Staff. The assistance of the Department of Insurance, the Cabinet for Health Services, the National Conference of State Legislatures, and the Council of State Governments is gratefully acknowledged.

Robert Sherman
Director

The Capitol
Frankfort, Kentucky
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SUMMARY

Background

Genetics is a rapidly advancing field, due to the Human Genome Project and the work of its affiliated researchers throughout the world. Scientists may be able to comprehensively “map” the human genetic code much sooner than was originally thought. However, one of the consequences of drawing this map is that outside entities, such as insurance companies, may be able to use this information to determine the insurability of individuals and groups.

Although the field of genetics has existed since the 1800’s, the Human Genome Project’s advances bring new information about the human genome every day. This information may determine, for individuals and their families, whether they have a certain disease, may have a propensity for disease, or may be a carrier for a genetic disease. There are many genetic tests that are of varying utility to individuals and their health care providers, in terms of their predictive abilities. Many of these tests are susceptible to misinterpretation and are not fully developed.

Conclusions

The field of genetics is extremely complex and so are the issues that arise from new discoveries in this area. The extent to which this new information may be used in determining people’s eligibility for insurance is subject to a variety of policy concerns, including concerns for privacy and confidentiality, and concerns for the solvency of insurers. Insurance companies generally believe that this information, should it become readily available to the insured, should be subject to disclosure to the insurance company on the same basis as other medical information, so that the insurance company can properly assess its risks. Consumers and health care providers generally believe that this information is the result of medical advances to help find cures for disease and should be kept confidential in order not to provide an unintended windfall to insurers and create an incentive for “genetic redlining.”

Underscoring the scientific complexity of genetics is a myriad of federal and state laws that address, with varying degrees of success, the issues involved in genetic testing and insurance. Many of the efforts that states currently make to address this issue may be preempted by federal law, but the federal laws generally leave it up to states to deal with groups that are not self-insured and to individuals and small groups. The U.S. Congress, however, is currently considering laws on medical information and managed care that may deal with this issue in a way that preempts state laws.

Kentucky has no laws specifically prohibiting genetic discrimination in life insurance, so life insurers in Kentucky may use information in any way that is allowed by other provisions of federal and state law. In 1998, Kentucky passed a law providing some protections for people having individual or small group health insurance and disability insurance and who may have had genetic tests or may have information about their genetic makeup. The law prohibits health and disability carriers from requesting disclosure or

requiring applicants, participants, or beneficiaries to disclose to the insurer a genetic test about the participant, applicant, or beneficiary. The law prohibits health insurers of groups and individuals from denying, canceling, or refusing to renew the benefits or coverage, or varying the premiums, terms, or conditions of the coverage on the basis of a genetic test for which symptoms have not manifested or on the basis that the participant has requested or received genetic services.

The law also provides that a health insurer in the large or small group or the association market may not use genetic information as a health status-related factor in establishing eligibility under those plans. The law also limits the use of genetic information as a pre-existing condition in group health plans, as long as there is no diagnosis of the condition related to the information. Eligible individuals going to individual health plans are protected from the use of this information as a preexisting condition if there has been no diagnosis of the condition related to the information. Non-eligible individuals in individual health plans are protected from the use of this information as a pre-existing condition to the same extent as people in group plans, except that the period of any creditable coverage's reduction of the exclusion period is limited to a policy that has benefits substantially similar to the benefits provided in the creditable coverage.

Despite these provisions, the law fails to define what is a genetic test, genetic information, or genetic services, or to provide other needed definitions. The current definitions promulgated by the Department of Insurance a narrow definition of these terms. Therefore, insurers may have access to a great deal of information about the genetic backgrounds of insureds and potential insureds. A survey of insurance companies indicated that most insurance companies use all the information available to them, including genetic tests, if these tests are in the insured's medical records. This information is easy to obtain, and much of the information is not covered under the restrictive definitions of Kentucky law described above. Importantly, as stated above, life insurers are not covered by any of these provisions.

Kentucky statutes on health insurance allow for higher rates for individuals with manifested symptoms of genetic disease, and many people with symptomatic genetic diseases may be placed in a high risk pool, so the effect of prohibitions against discrimination in individual insurance may be limited by the practical reality that the people in these plans may be required to pay more for their insurance because their diseases may be genetic in nature. Although the insurer may not use genetic information as a factor to deny eligibility, the higher rates may affect people's ability to pay for their insurance. Since the health insurance law institutionalizes different treatment of persons with some genetic disorders, it may create an incentive for insurance companies to classify people as having these diseases. There is nothing in the law that precludes health insurance companies from charging more for persons with genetic diseases, if symptoms have manifested themselves.

A related issue is whether health insurance companies should pay for genetic testing services, and what the impact of their involvement might be upon genetic services. There is some evidence from the study that health insurers are reluctant to pay for tests which may indicate the presence of a genetic abnormality, even if one member of a family has tested

positive for the disease. There is also a concern that genetic services offered by the public health system may be compromised if disclosure to insurance companies is not limited. Other insurance-related areas, such as the effect of genetic testing upon employment, were not addressed by the study, but the General Assembly may choose to study these issues in the future.

Recommendations

The study recommends the following:

1. The General Assembly may wish to consider whether the definitions of “genetic testing,” “genetic information,” and related terms are sufficient.
2. The General Assembly may wish to monitor continuously other initiatives on genetic testing.
3. The General Assembly may wish to begin a public dialogue to complete the information available to the General Assembly and to determine the extent, if any, of discrimination on the basis of genetic testing or information in Kentucky.

CHAPTER I

INTRODUCTION

Authorization, Scope, And Research Procedures Of The Study

1998 Senate Resolution 161 authorized a study by Legislative Research Commission staff of the impact of genetic testing on life, health, and disability insurance in Kentucky. The study resolution stated that the Human Genome Project was established to map the human genetic code, that the project continues to identify genes that may pinpoint individuals' likelihood of developing diseases, that genetic testing availability is becoming more widespread, and that health, life, and disability insurers may wish to use this genetic information in determining insurance rates and standards for insurability.

This study examines the issue of genetic testing in life, health, and disability insurance, and provides recommendations for the 2000 General Assembly.

The study was conducted by examining relevant literature on the subject, analyzing relevant state and federal laws and policies, contacting the Department of Insurance and Cabinet for Health Services for information on genetic testing and genetic services, performing a survey of selected health, life, and disability insurers in the state, and contacting health care providers and groups interested in the topic of genetic testing.

The Scientific Environment Of Genetic Testing

The "Mapping" Of The Human Genome

1998 RS SR 161 was influenced, in part, by the Human Genome Project's efforts to map the entire human genome. The human genome is the entire sequence of DNA of the human body. The Human Genome Project (HGP) is an international research project begun in 1990 as a joint project of the U.S. National Institutes of Health and the Department of Energy. The HGP has as its purposes the identification of all of the estimated 80,000 to 100,000 genes in human DNA, determination of sequences of the 3 billion chemical bases that comprise human DNA, storing of this information in databases, development of tools for data analysis, and addressing the ethical, legal, and social issues that arise from the project. With the help of this information, researchers and health care providers hope to be able to create tests, provide counseling, and develop clinical treatments for inherited medical disorders. However, there is a growing concern that this information about the human genetic code may be used to discriminate against people in the area of insurance.

Analysis of the human genome is the goal of a number of agencies throughout the world. The major players in the United States are the National Human Genome Research Institute at the National Institutes of Health and the Department of Energy, which has long been interested in the effects of radiation and other environmental hazards on genetic material. The Human Genome Project includes studies of simple organisms as well as research on human genetic material. Working with model organisms such as yeast, roundworms, fruit flies and mice, researchers are developing sequencing techniques adequate for tackling the 3 billion base pairs that comprise the human genome. The sequences themselves are valuable because these organisms have many genes in common with humans. But unlike humans, they can be manipulated experimentally to determine how genes function and are controlled.

Understanding And Diagnosing Genetic Disease

The human genome may contain as many as 100,000 genes. Knowledge of the exact locations and sequences of all of these genes and their regulatory regions has the potential to revolutionize the early detection and treatment of disease. About 4,000 genetic diseases are known, and genes influence susceptibility to many other diseases.

<http://genome.wustl.edu/gsc/Info/about.shtml>

Although the issue of genetic testing in our daily lives appears at first glance to be science fiction, the HGP has progressed at such a rate that issues involving the uses of this information may need to be dealt with more quickly than was originally envisioned. The National Human Genome Research Institute (NHGRI) stated in September 1999 that the first draft of the genetic blueprint of humankind would be complete by the spring of 2000. As the deadline for this project comes closer, the possibility that the genetic code may be mapped out has more significance. This means that other concerns, such as genetic testing's impact on insurance, may need to be addressed by policy makers. If the "map" of the human genome is known, there could be the potential for insurance companies to ascertain which people could be subject to genetic disorders, if the results of genetic testing and information are readily available to insurers. This possibility has prompted policy makers in the federal and state governments to take a close look at how genetic testing and information relates to insurance, as well as other areas such as criminal law, employment law, and research activities.

Why Are Genes Important?

A discussion of genetic testing in insurance would make little sense without some insight into how human genes are configured and how they work, and how genetic testing is being explored. The human organism is one of the most complex, and scientists are just now determining exactly how the human body works and what the genetic makeup of humans consists of. Genes may provide a clue to our past and future in a way that is unparalleled, and the possibilities of research in this area appear to be limitless. The issues, however, related to the use of this information in other contexts are hotly debated.

The National Conference of State Legislatures (NCSL) has put together a comprehensive legislative briefing book, “Mapping Public Policy for Genetic Technologies,” which also contains a primer on how human genes work and the science of genetics.

DNA is the ladder-like chain of *nucleic acids*, the double helix formed from just four basic nucleotide building blocks: adenine, cytosine, guanine, and thymine (usually abbreviated by their first letters: A, C, G and T).

These units-called *bases*-pair up to make the rungs of the DNA ladder: adenine always pairs with thymine (A-T); cytosine always pairs with guanine (C-G). Thus one side of the ladder always forms a complement of the other. Each complimentary rung is called a *base-pair*.

Instructions written in this four-letter DNA alphabet tell the cell how to make (or *express*) a particular protein.

Proteins, long chains of *amino acids*, are the cell’s main structural and metabolic components-the bricks, mortar, gears and motors of life.

A *gene* is the stretch of DNA that contains the instruction for a single protein. The exact succession of DNA bases that *translates* into a given protein is called the *gene sequence*.

Genes are strung together on *chromosomes*-tremendously long molecules of DNA tightly coiled to fit inside the cell. Human beings have 80,000 to 100,000 genes. Each human cell contains about 3 billion base pairs of nuclear DNA-a rich volume 3 billion characters long. Stretched out, the DNA in a single cell of one person would measure about 6 feet. Written on sheets of paper like this, this information would fill 2 million pages and make a stack about 650 feet high. All together, these 3 billion base pairs of DNA make up the human *genome*-the entire complement of genes and regulatory structures that characterize an individual or a species.

Source: NCSL Mapping Public Policy for Genetic Technologies

The possible combinations of human cells’ “building blocks” are infinite and provide for limitless variety in the human species. No person’s genes are “perfect”, however, and every person has potential “flaws” in his or her genes. It has been estimated that each person has between 5 and 30 variant genes that possibly could lead to a resulting medical condition, either in that person or that person’s offspring. Just because a person has a “defective” gene does not mean that he or she is actually going to develop a certain disease. Many of these genetic imperfections never lead to a disease. For example, some people may be “carriers” of genes that do not cause disease on their own, but require another gene, environmental factor, or other agent to “react” with the gene to cause a resulting medical problem.

According to the Centers for Disease Control and Prevention (CDC), gene “flaws” or genetic components have already been identified which play a role in childhood diseases, such as cystic fibrosis, sickle cell disease, and asthma; chronic diseases, such as cancer,

cardiovascular disease, and Alzheimer's disease; occupational diseases, such as some bladder cancers; and infectious diseases, such as HIV/AIDS. More than 8,000 genes with these variations have already been catalogued. Additionally, there are tests for more than 400 genes which are associated with rare metabolic disorders and syndromes as well as those which increase a person's susceptibility to disease. Many of these tests may determine whether a person who does not have any symptoms of a disease may at some point have the disease. If a person is more susceptible to disease by virtue of a genetic trait and the environment is conducive, then a person may have increased risk for other diseases.

Many different genes may be implicated in the development of a number of health conditions, including mental retardation, errors of metabolism, congenital anomalies, cancer, anemia, infections, diabetes, thyroid disorders, dementia, arthritis, and myocardial infarction. Many tests are available, however, for conditions, that if diagnosed and treated early enough and properly, may avoid life-threatening results. There are even programs underway to 'fix' defective genes through direct intervention, utilizing gene therapy.

Certain genetic defects are incurable, however, and lead to certain death. While there are genetic tests that may pinpoint specific flaws and link them to a disease, most genetic differences do not have a corresponding test. Additionally, for many tests, the predictions that may be made from these tests may not be exact and may not hold true for every person. The issues relating to these genetic advances are diverse and go beyond the scope of genetic testing and insurance, but may involve some of the same basic policy choices.

CHAPTER II

THE POLICY ENVIRONMENT OF GENETIC TESTING AND INSURANCE

There are many differing opinions as to whether genetic testing and genetic information should be available to insurance companies. These conflicting considerations regarding genetic testing may be compounded by federal and state laws that may not be clear to the public or insurers, or which may not be entirely applicable to genetic testing and the information that may be gleaned from it. The gene “map” has been referred to as a “future diary,” which may have the potential to lay out the person’s health future as well as that of his or her family for generations to come. Medical science is in the process of developing new ways to read and possibly redraw this “map” with treatment options, which may include lifestyle choices, genetic alterations, counseling, or a combination of approaches. Assuming that the “map” or “diary” of our genes is accurate, who gets to read it?

For many, genetic testing can be the key to leading a relatively healthy existence. Studies have indicated that many in the U.S. would take advantage of genetic testing if it were readily available to them. A 1998 American Medical Association (AMA) study found that 59% of Americans are somewhat or very likely to take advantage of genetic testing. For others, genetic testing may raise fundamental concerns about privacy. Despite the public eagerness to take advantage of new technology, many are afraid of the possibility that the information taken from testing may be used against them. This fear is demonstrated by the AMA survey cited above, indicating that nearly 7 out of 10 Americans are somewhat or very concerned that genetic information may be used against them by either their employer or health insurance provider. Public concerns may be heightened by laws and regulations which are not well defined.

Medical Information Privacy

The issue of protecting genetic information is being debated against the backdrop of the larger issue of general medical information privacy. Although medical information has long been considered by patients to be private, many believe that the lack of a coherent system of state laws and the absence of a comprehensive federal law on the topic has rendered much medical information subject to scrutiny by employers, insurance companies, and others outside of the traditional concept of the physician-patient relationship. In the context of this broader discussion, the issue of genetic testing has been termed by some to be a subset of the bigger issue of who can access one’s medical information, when, and for what purposes. The question, these commentators believe, should be the broader question of what privacy interests exist for medical information in general, and whether people should have a right to keep this information personal and confidential. These commentators believe that there should not be “genetic exceptionalism,” as it is impossible to define with precision what information is genetic; all medical information is unique and therefore should be subject to the same protections. Additionally, there is a question of fundamental fairness in terms of treating a disease with a genetic component differently from a disease without such an origin.

Others believe that genetic information and the results of genetic tests, unlike other kinds of medical information, should be more closely guarded, as it is uniquely identifiable with a particular person; may be highly predictive of future conditions; is inherently stable information and does not usually change over time; can provide information about entire families, as opposed to just one person; and may be more likely to be misused and misinterpreted than other medical information. The ramifications of this possible misunderstanding or misuse of genetic information has broader scope than the context of insurance, although it is vital that insurance companies and insureds understand what, if any, meaning can be taken from genetic information. There is always the possibility that one “flawed” gene may not mean that a concomitant medical problem will exist. However, there may be the potential for stigmatization of that person because of a perceived problem, either inside or outside the context of insurance. There is also the issue of effective counseling of the person and that person’s family as to the problems which might be identified through testing. The area is complex and fraught with intense controversy. This is a moving target that scientists and medical professionals continue to try and hit, and policy-makers may wish to address it as well.

Policy Choices In Defining Genetic Testing And Genetic Information

The possibilities and consequences of genetic testing and the use of genetic information continue to change along with the advancing science of genetics. Some argue that legislation or regulations that may be appropriate for other forms of medical information may be inadequate to the task of creating a legal framework for advancing technology in the area of genetic testing. Genetic testing is a rapidly changing field and the information that it may offer in the future may mean that a continuous reevaluation of the law is necessary. In the area of legislative policymaking, laws regarding genetic testing are difficult to draft, both because of the complexity of the science involved and the difficult issues that may be engendered by a discussion of genetic testing and its implications.

The first issue involves grappling with the actual process of genetic testing and looking at what information may be derived from it. The actual procedure of genetic testing or providing screening for genetic traits has been termed “the process of scanning an individual’s genetic composition to determine if the individual has genetic material rendering him or her susceptible to developing or transmitting a genetic defect or disease.” Genetic testing, as most people perceive it, is performed through extraction of DNA obtained from a blood sample, which is sequenced and then compared to other known sequences. The individual may or may not have genes or a group of genes that have a variation, which is scientifically known to cause or make the person more likely to have a disease.

According to commentators, genetic testing can pinpoint the following scenarios (for disorders that are proven genetic disorders):

- A person who has or is certain to develop a particular genetic disease;
- A person who does not have a genetic disease, but is a carrier of a disease; and
- A person who has a genetic predisposition to developing a particular disease in the future.

One commentator has described the range of genetic tests as follows:

Genetic tests can include scientifically precise testing such as direct molecular manipulation of genetic material, or simply an individual's medical examination. As commonly understood, however, "genetic testing" can be defined in terms of one or more of the following current genetic tests:

- (1) Direct and indirect determination of "altered" DNA composition using molecular genetic techniques to analyze a blood or skin sample (ex: tests for cystic fibrosis or adult polycystic kidney disease);
- (2) Microscopic examination of chromosomes from a blood or skin sample to detect an abnormal number of chromosomes or chromosomes with aberrant structures (ex: Down's syndrome, Turner's Syndrome); and
- (3) Chemical, immunochemical, or biochemical analysis which detects genetic conditions by measuring chemicals or enzymes in the blood or other body samples (ex: Tay-Sachs, sickle-cell anemia, PKU).

Eric M. Holmes -- Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project

As stated above, some of these tests are extremely accurate and precise, and others are not as well developed. While most think of a "genetic test" as the testing of a sample of DNA, there are many types of tests which do not involve direct DNA testing and that may have genetic components or may indicate genetic traits that provide clues to possible inherited diseases. For example, a cholesterol test is not commonly considered to be a "genetic test," as it does not involve testing DNA. However, the test could provide information as to the genetic predisposition that someone has to a disease. Additionally, as commentators have pointed out, a physical examination can provide information about possible genetic diseases, and answers to questions regarding family history can point to a genetic heritage that may include such problems. For some diseases, the mere fact that a person is of a certain heritage may mean that they are more likely to have a certain genetic condition. Policymakers, therefore, need to decide whether they want to define "genetic test" to include more than just DNA testing, and whether the definition captures all of the scientific and policy scenarios intended.

Competing Positions On Genetic Testing In Insurance

While many health care providers and patients believe that no genetic testing or information should be used by insurance companies, insurance companies' position has generally been that the predictive ability of genetic testing and information is such that there needs to be some disclosure to insurance companies of the fact that genetic testing has occurred or that genetic information has been received by the patient.

Recommendations Of The National Task Force On Genetic Information And Insurance

Many researchers involved in the HGP have looked at the issue of genetic testing in insurance, with a particular emphasis on health insurance. In 1993, the Joint National Institutes of Health-Department of Energy Working Group on the Ethical, Legal, and Social Implications (ELSI) of Human Genome Research formed the Task Force on Genetic Information and Insurance, which made the following recommendations related to genetic testing and health insurance:

1. Information about past, present, or future health status, including genetic information, should not be used to deny health care coverage or service to anyone.
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 service appropriate for the healthy to the seriously ill.
3. The program of basic health services should treat genetic services comparably to nongenetic 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.
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.
5. Participation in and access to the program of basic health services should not depend on employment.
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.
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.

Insurance Companies' Perspective

Different types of insurance may have common issues involved in genetic testing, and there may be other issues that depend on the type of insurance under consideration. There are common elements to the concept of insurance, however, which has been described as “the arrangement for the transference of the risks of fortuitous losses to an insurer and the distribution of those risks among insureds who pay a premium to a common fund.” Insurers utilize underwriting, which seeks to measure the risks involved in offering insurance to a particular group or person and to charge a premium in exchange. In general, for most types of

insurance, large groups are not subject to individual underwriting because of the ability of the insurer to spread costs over a large group. These large groups are generally rated, at renewal, on the experience of the group as a whole, not on individuals. Therefore, commentators have stated that the impact of genetic testing on larger groups of insureds would be minimal, both for insurance companies and insureds in those groups, because the insurance company can spread the risk over a larger group of people, and the people in the group are not individually underwritten for coverage. The focus of genetic testing's impact on insurance falls primarily on the individual and small group markets.

The insurance industry states that the basic premise of insurance is to assess risks, define which risks are subject to which costs for insurance, and determine whether a given insurance will provide compensation for these risks in certain individuals or groups. Insurance, whether life, health, or disability, it is argued, is to provide for financial protection against losses that cannot be foreseen, and if an insured has any information that the insurance company does not have, this will not allow for risks to be properly insured against. The insurance industry states that insurance is a business and that the industry as a whole will suffer if certain persons know what their risks are and obtain insurance without providing full disclosure of all things that are material to the assessment of that person's risk, including prior genetic tests or information.

Since the insurance market for life, health, and disability insurance is a private, voluntary one in which no one is required to have insurance, the insurance industry as a whole is concerned about adverse selection. Adverse selection is a phenomenon that occurs when insured have information about their insurability that may put them at a greater risk, and the insurance company does not have knowledge of this increased risk. Insurers say that this may lead to an upward spiral of rate increases, which discourages people of low risk from obtaining insurance, until the only people in the pool of insurance are those with the highest risk. Insurance companies state that individuals may remain uninsured until they realize that they may have a medical problem, as revealed by a genetic test or information, and then obtain insurance. The ability of each company to assess risks with respect to a particular type of insurance is of concern to insurers.

Insurance companies get medical information from different sources, the most common of which frequently involve the insured's assent to obtaining information as a prerequisite to issuing coverage. Applicants for insurance, when applying for coverage, may sign a waiver that consents to the release of their medical records to the company to which they are applying. Applicants who assent to this release may have their medical information placed in this database, which may then be used by other insurers. Many insurers utilize a common data bank, such as the Medical Information Bureau or MIB. This data bank is an insurance-industry run data bank, which is accessible to about 800 companies in the United States and Canada. Members may input medical data that they have about individuals, and all members have access to the information contained in the database.

Health Insurance. Health insurance provides payment for treatment of medical conditions. Many health insurers make explicit reference in their policies for reimbursement for genetic testing and services, including counseling and treatment, and payment for testing

is usually made only if the patient displays symptoms of the condition for which the test was done. The insurer may contend that the condition is pre-existing, if a test is performed prior to the beginning of coverage. Group health insurance is risk classified either on the basis of the group's own claims experience or by data from the claims experience of other similar groups in the same industry, and premium rates are also set according to these factors. For individual health insurance coverage, the premiums are often set according to the individual's age, sex, and geographic residence, which insurers contend are reliable factors that may show the kind of claims experience and medical expenses that a person may have.

If a certain genetic test reveals something that is treatable, that health insurance plan may have to pay for those treatments. Conversely, a test may show that the health insurance plan should pay for an alternative treatment that may be less costly. Treatment for some genetic diseases may be extremely costly and long-term, while others may not be. Additionally, genetic disease carriers would not have to be treated, although testing may be covered under a policy.

According to the U.S. Census Bureau, in 1998, 70.2 % of people having health care coverage had private health insurance, and most people (62%) having private health insurance obtained insurance from an employer. Of the people having private health insurance, most have it through a large employer. According to the U.S. General Accounting Office, most large companies (those with more than 100 employees) offer health insurance to their employees, and the larger the employer is, the more likely that its employees are offered health insurance. According to a 1998 LRC Report, in 1997 there were around 165,000 people with individual health insurance, 465,000 people with small group insurance, 1.8 million people with large group insurance, and 570,000 people uninsured in Kentucky.

Life And Disability Insurance. Life insurance provides payments to beneficiaries upon the death of the insured. Since it insures against the catastrophic event of death, life insurance may be implicated only by those genetic tests which show a propensity for disease that may be life-threatening or life-shortening. Disability insurance provides for payments to the insured if he or she becomes disabled and cannot work. In Kentucky, disability insurance is included in the statutory definition of life insurance (KRS 304.5-020). With disability insurance, upon a claim of disability, a certain percentage of the insured's former income is paid to the disabled individual. The individual may have short- or long-term disability insurance and may purchase disability insurance in conjunction with life insurance. In 1995, the National Institutes of Health reported that in 1993, 10.6% of the U.S. population had a chronic disabling condition (that is, a long-term condition), and as many as 9 million people in the U.S. are unable to work, attend school, maintain a household, or perform activities of daily living. According to the University of Kentucky's Center for Rural Health, approximately 11.5% of Kentuckians ages 16 to 64 had a work disability

According to NCSL, life and disability income insurance may be underwritten either individually or on a group basis, but the majority of life and disability insurance policies are individual in nature. For both life and disability income insurance, the company performs medical underwriting and arrives at the cost of these policies at the start of the contract. After the policy is issued to the insured, neither the terms of these policies nor the premiums can be

changed except in accordance with the terms of the policy, regardless of changes in the nature of the insured risk or the length of time the contract is in effect. Generally, life and disability income policies cannot be terminated, except for nonpayment of premiums or for misrepresentations or fraud. According to NCSL, many group life and disability income policies have provisions allowing a change in premiums for a group as a whole. An individual generally may not be singled out, however, for premium increases based on health factors. There may be policies that are in place for a specific term. Most individual policies use risk classification and underwriting, and insurance companies attempt to put applicants for coverage into groups or classes, with a class consisting of individuals who have similar levels of risk, as actuarially determined by the company. In this risk classification system, the members of a particular class pay the same premiums, which represent the relative risk of the insured.

For life insurers, most group policies are issued without medical underwriting, while individual policies may require medical tests. According to one estimate, about 97% of all applications for ordinary life insurance are accepted, with 3% being rejected, and less than 5% of those accepted have to pay higher than standard premiums. A 1991 report by the U.S. Bureau of Labor Statistics stated that most medium to large size employers offer life insurance as a part of their employment packages, and 94% of employees in medium to large size businesses participated in these plans in 1989.

Consumers' And Health Care Providers' Perspective

Many health care providers and patients take the position that any information relating to genetic testing should be private and confidential, and that the misuse of this information may lead to discrimination by insurance companies or other outside entities. According to one insurance commissioner:

Some consumer groups advocate a much broader definition of genetic testing, which would have the effect of prohibiting inquiries into the applicant's family medical history, or even the ages and health of an individual's parents. Consumer groups believe that a narrow definition of genetic testing, which limits the term to laboratory tests of genes or chromosomes, would leave large segments of the population unprotected from discriminatory underwriting. A narrow definition leaves insurers free to use information about genetic abnormalities that might be contained in blood tests, for example.

(Jack Ehnes, Testimony of the National Association of Insurance Commissioners' Special Committee on Health Insurance before the Committee on Labor and Human Resources of the United States Senate on "Genetic Information and Health Care", May 21, 1998.)

Consumers and health care providers state that the HGP was designed to further medical science and the understanding of complex diseases, and should not be used for the purpose of providing insurance companies with a way to pick out which people are healthiest and insure them, while disregarding those with a "questionable" genetic makeup. They state that requiring testing, or requiring disclosure of testing or genetic information, will result in

those persons and families who need insurance the most being denied the opportunity to purchase and retain it. These proponents of confidential treatment of genetic testing and information state that there is a social mission inherent in insurance that should allow for the “high risks” of a few people to be distributed across a larger group of people. Additionally, they feel that the burden of being a higher risk individual may fall more heavily on those who have small group or individual insurance, as these persons have less ability to spread their risks among others. Insurance companies, they state, should not be able to determine beforehand who might get a disease related to genetic information and thus refuse to insure a person or raise that person’s insurance rates, regardless of the type of insurance involved.

Consumers and health care providers also cite the prevalence of genetic disorders and state that these may have a greater impact on particular groups, such as children, or particular ethnic groups. They argue that limiting insurance coverage for this small population may have the effect of creating a “genetic underclass,” even though the small numbers of people with these diseases would make it easier for insurers to effectively spread risks over a larger group of insureds. Additionally, they state that limiting insurance coverage may limit treatment options and force people into the health care safety net because they are uninsured.

For example, the CDC reported in 1997 that deaths from genetic diseases accounted for .3% of all deaths in the United States, and that deaths from birth defects accounted for .9% of all deaths in the United States. The study stated that birth defects were the leading cause of infant mortality, accounting for about 20% of all infant deaths, showed that a substantial percentage of deaths of older children were related to birth defects (15.5% among 1 to 4 year olds, 8% among 5 to 9 year olds, and 6% among 10 to 14 year olds), and that the percentage of deaths associated with genetic diseases was reported in less than 1% of total infant deaths, with the highest being among pediatric age groups (aged 1-14 years old).

Overall, the deaths associated with birth defects and genetic diseases among pediatric age groups (aged 0-14 years old) were reported in about 21.5% of total number of death among pediatric age groups. The study stated that this information may be incomplete because of problems with getting mortality data reported and with concurrent birth defects and genetic diseases that may coexist in one person. Another study looked at two states and analyzed pediatric hospitalizations, and this data showed that birth defects and genetic diseases account for a high percentage of pediatric hospitalizations, and these hospitalizations are proportionally more costly than other types of pediatric hospitalizations. The rates for hospitalizations that were related to birth defects and genetic diseases were higher for infants compared with older children, and they were higher for black children compared with white and Hispanic children. Many studies have noted problems with getting accurate information about the prevalence of birth defects and genetic diseases among children, in particular, and of the costs of treatment, and that this information is crucial in determining the health care and treatment strategies that may be employed and the policy decisions about insurance that may have to be made. Other studies have found that the costs of hospitalization related to birth defects and genetic diseases is largely borne by the public sector.

Another issue raised by health care providers and consumers is the effect of the treatment of genetic testing and genetic information on genetic screening programs and

research efforts. Genetic screening programs in place in states, including Kentucky, are designed to provide families with ways to identify if they have heightened risks of having a child with a genetic anomaly, and also to guide families to resources to utilize in the event that their child has a genetic disorder. These screening programs provide testing for many conditions that fall into the following counseling/screening categories:

- *Unifactorial counseling*-for single gene disorders;
- *Autosomal dominant disorders*-for disorders arising from the dominant gene;
- *Autosomal recessive disorders*-for disorders arising from the recessive gene;
- *Multifactorial Counseling*-for disorders arising from a combination of affected genes; and
- *Population screening*-for disorders arising from a particular ethnic background that has shown to have a high propensity for genetic disorders.

Proponents of screening programs state that it is increasingly difficult to get people to agree to testing, due to increasing anxiety over the potential use of these tests, and this problem may be compounded if the results are not kept confidential. Additionally, professionals in the area of genetic screening and counseling state that families need to have accurate, as well as compassionate, treatment of any information that comes from genetic testing or screening.

Research advocates state that medical research involving genetics is only as good as the amount of concise information that may be gleaned from the largest number of people. Researchers say that the fear of discrimination or the use of testing information outside of the research context may prevent enough people from participating in genetic research, thus limiting the prevention and treatment strategies that are developed. Researchers also state, however, that too strict limitations on the uses of genetic information may impede medical research by forcing researchers to obtain additional consent and provide additional disclosures, and by preventing the sharing and exchange of data among researchers. A GAO report found that medical researchers often need access to personally identifiable information, but external oversight of research is often limited, sometimes resulting in unintended breaches of confidentiality.

CHAPTER III

THE LEGAL ENVIRONMENT OF GENETIC TESTING AND INSURANCE

One fundamental issue to address in the process of formulating policy choices in the area of genetic testing and insurance is the question of defining “genetic testing,” “genetic information,” and related terms. These would appear to be simple definitions. However, there are many opinions concerning which tests should be considered to be “genetic testing,” and what should be considered “genetic information.” The question of defining these and related terms is extremely important, as a broad definition may include things which should not be considered genetic tests or information, and a narrow definition may exclude these. The definitions may unintentionally exclude groups that policymakers believe should be protected, or may sweep too broadly and include commonly accepted insurance practices that are recognized to be useful in assigning risk. In the context of writing laws or regulations regarding genetic testing in insurance, these definitions are crucial. A related question would be the “staying power” of these definitions, as the science underlying today’s definitions may be changed tomorrow. Also, policymakers may wish to address the issue of who determines the definitions used, for example, whether it is the legislative or executive branch.

The issue of genetic testing is made more complex because of federal laws that may restrict what states may do to regulate insurance.

Federal Laws, Regulations and Other Initiatives Relating to Genetic Testing

An additional question for Kentucky legislators in examining the issue of genetic testing in health, life, and disability insurance is whether the federal government will look to occupy the field of genetic testing legislation by enacting federal laws. If this occurs, state legislation on the subject may be rendered ineffectual because of preemption. There are numerous federal provisions and proposals on the subject of genetic testing that may limit what Kentucky can do to affect this issue.

Federal Employee Retirement Income Security Act (ERISA)

The Employee Retirement Income Security Act (ERISA) preempts state legislation relating to any self-funded employee benefit plan, which includes those plans providing fringe benefits such as health, life, and disability coverage for their employees. While another federal law, the McCarran-Ferguson Act, specifically grants states the right to regulate insurance, the preemption clause of ERISA, §514(a), 29 U.S.C. § 1144(a), broadly states that ERISA provisions “shall supersede . . . State laws” to the extent that those laws “relate to any employee benefit plan.” The saving clause, §514(b)(2)(A), 29 U.S.C. § 1144(b)(2)(A), exempts from preemption “any law of any State which regulates insurance.” The caselaw relating to ERISA preemption of state law claims is complex. Any state laws that attempt to regulate genetic testing or information usage by health, life, or disability plans which are subject to ERISA will be preempted. The issue of whether a particular state law subjects self-

insured plans to a standard of conduct which is preempted by ERISA is the subject of much litigation.

However, there are several bills in Congress that would provide for a federal standard for self-insured health insurance plans. The 1999 Congress is in the midst of tackling the broader issue of managed care reforms and has held hearings on several bills, some of which would prohibit a health care plan from discriminating against enrollees in the delivery of health care services on the basis of race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment. The U.S. Senate approved S. 1344 on July 15, 1999, and the House of Representatives approved H.R. 2990, which incorporated the provisions of H.R. 2723, on October 7, 1999. As passed in the House, H.R. 2990 would preempt state laws regulating health plans that are not equivalent or stronger. State laws that may be affected include grievance and appeals procedures, any consumer protection measures, and benefits requirements. There are no provisions in the House bill specifically related to genetic information or testing.

S. 1344 does contain provisions regarding genetic information. The bill would prohibit group premiums from being increased based on the genetic information of one or more individuals in the group, including family members. Under the Senate bill, a plan may request, but not require, only that genetic information that will assist in diagnosis, treatment or payment, and cannot request or require any other genetic information. In the bill, genetic information includes genetic tests and family medical history, but cholesterol tests are not considered genetic tests. The provision would also apply to individual plans. These bills are currently in conference.

Americans with Disabilities Act (ADA)

The Americans with Disabilities Act of 1990, Pub. L. No 101-336, 104 Stat. 327 (1990) may provide some protections in the arena of genetic discrimination, albeit in the arena of employment. The ADA may provide limited federal protection against genetic discrimination in employment-related health insurance plans, however, its application would be limited by ERISA. While it does not specifically mention genetics, some commentators state that it clearly covers expressed genetic disorders to the same extent as impairments without a genetic component. The law, however, applies only to employers with 15 or more employees, and other commentators have noted that it would not protect against genetic discrimination that was actuarially justified.

A recent article stated that many researchers and policymakers have opined that the ADA may protect people with the following genetic abnormalities:

genetic carrier states (e.g., a cystic fibrosis carrier), disease predispositions (e.g., a marker for Huntington disease), and inherited diseases (e.g., sickle cell disease). Certainly, a person with symptomatic disease, whether of genetic or other physiological origin, would be protected by the ADA if the disease caused a serious impairment of a major life activity. At the other extreme, an individual who carries one copy of the gene for a recessive disease has no physical disability, either current

or future. Genetic carriers, therefore, could be covered only if the courts found them to have serious reproductive impairments or if they were regarded as disabled.

This commentator stated that, in light of recent U.S. Supreme Court cases interpreting the ADA, genetic and other predispositions to disease might be considered covered disabilities.

Health Insurance Portability and Accountability Act (1996)

Prior to 1996, there were no provisions in the federal law that directly controlled the use of genetic testing or genetic information with regard to health insurance. With the passage of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), the federal government created new protections for insureds in terms of the accessibility, portability, and renewability of health insurance. The law focused on people with group health insurance coverage through an employer or union, which encompasses the majority of people with private health insurance.

HIPAA prohibits group health plans from using any health status-related factor, including genetic information, as a basis for denying or limiting eligibility for coverage or for charging an individual more for coverage. The law also requires states to provide that eligible individuals, which are those who have lost group coverage, have access to at least two individual market insurance products, and states may require individual market carriers to guarantee access to certain insurance policies or create an alternative mechanism.

The law provides some protections for genetic information, but these provisions only apply to group coverage. HIPAA provides that a health insurer cannot discriminate against an individual having group coverage on the basis of genetic information by increasing his or her premium, and the premium for coverage cannot be greater than a premium for a “similarly situated individual”. Insurers can, however, require all group members to be given a higher premium based on genetic testing information of one person. Under HIPAA, an insurer cannot use genetic information as a basis for establishing rules of eligibility that exclude an individual, or a dependent of the individual, from eligibility under a group health plan. However, the insurer can require an individual to submit to a genetic test.

The federal HIPAA regulations define “genetic information” as:

. . . information about genes, gene products, and inherited characteristics that may derive from the individual or a family member. This includes information regarding carrier status and information derived from laboratory tests that identify mutations in specific genes or chromosomes, physical medical examinations, family histories, and direct analysis of genes or chromosomes.

Currently, there are no comprehensive federal health information privacy standards. HIPAA provided that Congress was given the authority to enact federal privacy legislation by August 21, 1999, and if it failed to enact such legislation, the Secretary of Health and Human Services was required to promulgate regulations establishing electronic privacy

standards by February 21, 2000. As of August 21, 1999, Congress failed to enact privacy legislation.

Another aspect of HIPAA relating to genetic testing was an incentive for Congress to pass a medical records privacy bill. In HIPAA, Congress placed a deadline of August 21, 1999 to pass such legislation. Since Congress' self-imposed deadline to pass a medical records privacy bill has passed and Congress has not enacted any legislation, the Department of Health and Human Services' Office of the Assistant Secretary for Planning and Evaluation (ASPE) drafted regulations to meet another February 2000 deadline. On October 29, 1999, President Clinton issued proposed medical records privacy regulations, which must be finalized by the Health and Human Services Administration by February 2000 to meet the HIPAA deadline. These regulations will address only the privacy of electronically transmitted medical information, because HIPAA does not authorize regulations on broader issues of medical records privacy. The proposed regulations state that the federal law will preempt state laws only where the state and federal laws are contradictory and the federal regulation is judged to establish more stringent privacy protections than the state.

Fair Credit Reporting Act (FCRA)

In 1995, the FTC's Bureau of Consumer Protection determined that the Fair Credit Reporting Act requirements apply to insurance investigations, and that consumers applying for health, disability and life insurance have the same guarantees that protect consumers from unfair treatment in credit and employment investigations. According to the Federal Trade Commission (FTC), the Medical Information Bureau (MIB) collects and furnishes information on consumers to all MIB members for use in the insurance underwriting process. In addition to an individual's credit history, data collected by the MIB may include medical conditions, driving records, criminal activity, and participation in hazardous sports, among other facts a patient may have revealed to a physician. According to the FTC, MIB's member companies account for 99 percent of the individual life insurance policies and 80 percent of all health and disability policies issued in the United States and Canada. However, companies still share data derived from medical information.

Other Federal Initiatives

In 1998-1999, there were multiple bills proposed in Congress dealing specifically with the subject of genetic testing in insurance, however, none of the bills have passed. In June, 1998, the U.S. Secretary of Health and Human Services created the Secretary's Advisory Committee on Genetic Testing. This group, convened in July, 1999, is charged with advising the Secretary on genetic testing issues and is composed of experts on genetic testing. This advisory committee is expected to provide input to Congress as to the scope of genetic testing protections that should be enacted, and its recommendations are due to Dr. David Satcher, Assistant Secretary for Health and Human Services and Surgeon General, on March 15, 2000. Additionally, researchers participating in the Human Genome Project continue to study the implications of genetic testing in society.

State Laws on the Use of Genetic Testing

There have been state laws regarding forms of genetic testing since the early 1970's. These laws were limited to a few selected conditions or traits, such as sickle-cell anemia, Tay-Sachs, or hemoglobin C. The first state to enact a genetic testing provision aimed at limiting the use of such information in employment was North Carolina, in 1975. The law prohibited employers from discriminating against employees, based on the sickle cell trait or hemoglobin C trait. Florida, Louisiana, New Jersey, and New York followed suit with anti-discrimination laws that also provided protections for persons with these inherited traits. In 1986, Maryland passed a law covering a wide range of diseases. Oregon, in 1989, included "genetic screening" in prohibitions against employers' requiring an employee to submit to medical tests as a condition of employment.

Following this initial legislation, the state legislatures in the 1990's introduced and passed a number of bills relating to genetic testing and insurance. Most of these laws prohibit insurance companies from using genetic information in health insurance in order to underwrite individuals for coverage. Many also extend to life and disability insurance. Many bills also limit the use of genetic testing or information by employers. Most recently, legislation provides for ownership or property rights in genetic information or other kinds of medical information. Currently, 37 states have some provisions regarding the use of genetic testing or information in insurance. All of these laws cover health insurers, with a smaller percentage also covering life and disability insurers. Some of the newest laws also cover long-term care insurance, which provides for payments for care in nursing facilities. These laws are summarized in the appendix to this report.

Definitions of Genetic Testing

There are many definitions which may broaden or narrow the application of these laws. According to NCSL, most statutes that define "genetic test" do so as follows:

The analysis of DNA, RNA, mitochondrial DNA, chromosomes, genes, or gene products to look for the presence or absence of genes, variations, alterations, or mutations of the DNA, RNA, mitochondrial DNA, chromosomes, genes or gene products.

NCSL points out that the definitions used by states generally fall into these two general categories, broad and narrow, and the definition above would be considered to be a narrow one. An example of a "broad" definition of genetic test, as given by one commentator, would be Ohio's definition, which defines a genetic test or screening to mean:

A laboratory test of a person's genes or chromosomes for abnormalities, defects, deficiencies, including carrier status, that are linked to physical or mental disorders or impairments, or that indicate a susceptibility to illness, disease, or other disorders, whether physical or mental, which test is a direct test for abnormalities, defects, or deficiencies, and not an indirect manifestation of genetic disorders.

Commentators have noted that even though this definition is broadly stated, it excludes family history and the individual's medical history, which may have genetic components. Prior to 1996, no states included family history or medical history in the definition of genetic test, but more recently states have looked at including family or medical history as well.

A "narrow" definition of genetic test would be a definition which is limited to a test for DNA, such as Texas and Georgia's definitions. Texas defines a "genetic test" as follows:

a laboratory test of an individual's DNA, RNA, proteins, or chromosomes to identify by analysis of the DNA, RNA, proteins, or chromosomes the genetic mutations or alterations in the DNA, RNA, proteins, or chromosomes that are associated with a predisposition for a clinically recognized disease or disorder. The term does not include:

- (A) a routine physical examination or a routine test performed as a part of a physical examination;
- (B) a chemical, blood, or urine analysis;
- (C) a test to determine drug use; or
- (D) a test for the presence of the human immunodeficiency virus.

Many research groups studying genetic testing and its potential ramifications have grappled with defining this term as well. For example, as a part of the Human Genome Project, a Working Group on Ethical, Legal, and Social Implications (ELSI) of Human Genome Research was convened. That group described a genetic test as follows:

Genetic test--The analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn, and carrier screening, as well as testing in high risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes. Tests conducted purely for research are excluded from the definition, as are tests for somatic (as opposed to heritable) mutations, and testing for forensic purposes.

The National Association of Insurance Commissioners (NAIC) also looked at the issues involved in genetic testing in insurance, but their Genetic Testing Working Group did not arrive at a conclusion as to which definitions should be used, although it did recommend a "working definition" identical to the Ohio definition set forth above. In response to the federal Health Insurance Portability and Accountability Act (HIPAA), the NAIC is currently drafting model legislation, the Small Employer and Individual Health Insurance Availability Model Act, to implement the provisions of this act, and this draft of the model legislation contains a definition of "genetic information" which has been taken from the federal HIPAA regulations. This model act has not been finalized.

There are other definitions of "genetic test" that may include the predisposition to genetic diseases found by genetic tests. NCSL points out that these broader definitions may

also indirectly exclude routine tests, which may in fact provide information on genetic traits. Still other definitions focus on testing that is done prior to the development of symptoms for a particular disease. These definitions may exclude persons who are “carriers”; that is, they will never develop a disease but may pass the gene for a disease on to any offspring.

Definitions of Genetic Information

Similarly, the definition of “genetic information” is difficult to pin down. One may obtain information that might be considered “genetic information” through a family medical history, during a physical examination, or a routine laboratory test. These types of information may show evidence of inherited characteristics, although they are not usually considered to be “genetic information” by laypersons. The information may also be obtained through DNA analysis or other genetic tests, as described above. NCSL states that the common definition of “genetic information” is as follows:

Information about genes, gene products, or inherited traits that may derive from an individual or family member.

NCSL states that this definition is broad enough to include information that goes beyond health matters to include appearance and personality and may include information that does not necessarily involve genetic diseases, but may involve diseases with strong genetic, but also environmental, components. However, some definitions that limit “genetic information” to the information obtained through DNA analysis may exclude information from these less “technical” and more traditional ways of obtaining information. An example provided by NCSL is of a person whose father or brother had Huntington’s disease, which would mean that the person has a 50% chance of having that gene. On the other hand, a definition for genetic information which was limited to the information derived from a genetic test would exclude that information, and thus a family history that contained this information would not be protected under a law that defined genetic information in this way.

Varying Perspectives on Definitions

According to one insurance commissioner who reviewed the topic, no generally accepted term precisely defines “genetic testing.” Insurers wish to have a more restrictive definition of genetic testing that would limit the term to such tests as the laboratory testing of human DNA or chromosomes because it is hard to distinguish genetic conditions from other medical conditions and genetic tests from other medical tests. The insurance industry states that genetic information and genetic tests include information and tests which have always been employed in the underwriting process, such as an individual’s height and weight, and tests for high blood pressure and cholesterol. In the opinion of insurers, a broad definition of genetic testing would impede their use of all medical information and would fundamentally weaken the risk classification process.

In contrast, some consumer groups advocate a much broader definition of genetic testing, which would have the effect of prohibiting inquiries into the applicant’s family medical history, or even the ages and health of an individual’s parents. Consumer groups believe that a narrow definition of genetic testing, which limits the term to laboratory tests of genes or chromosomes, would leave large segments of the population unprotected from discriminatory underwriting. A narrow definition leaves insurers free to use information about genetic abnormalities that might be contained in blood tests, for example.

CHAPTER IV

ASSESSING THE IMPACT OF GENETIC TESTING ON LIFE, HEALTH AND DISABILITY INSURANCE IN KENTUCKY

Kentucky Laws and Regulations Relating to Genetic Testing in Insurance

Prior to 1998, Kentucky had no statutes or regulations specifically relating to genetic testing in insurance. In 1998, the General Assembly enacted certain laws that apply to health and disability insurers. There are no provisions in Kentucky law that specifically apply to life insurers' use of genetic tests or information.

Prior to 1998, there were other provisions relating to genetic testing of other kinds and genetic conditions that had been enacted. These are:

- Genetic testing for paternity, in order to determine child support obligations: KRS 405.430 and KRS 406.005 et seq;
- DNA testing for certain convicted felons and persons incarcerated and centralized database for DNA identification records: KRS 17.170 and 17.175;
- Dissemination of post-adoption information about a medical or genetic condition affecting an adopted person: KRS 199.525;
- Sickle Cell Disease Detection: KRS 402.310 to 402.340; and
- Screening for inborn errors of metabolism: KRS 214.155.

Kentucky has a system of genetic screening called the Newborn Screening and Detection Program, pursuant to KRS 214.155, that provides screening for several inherited diseases, including sickle cell anemia, galactosemia, congenital hypothyroidism, and phenylketonuria (PKU). Genetic testing and counseling for these diseases and others are available from hospitals, the University of Louisville and the University of Kentucky, and from individual health care providers. The federal Maternal and Child Health Block Grant program and state general funds provide for genetic services through the state's medical schools and other participating providers. Additionally, the University of Kentucky and University of Louisville are involved in many long-range research projects and clinical studies that involve the genetic basis of diseases, including Parkinson's and Alzheimers' disease. The University of Kentucky has a comprehensive cancer registry program that provides research and data on the prevalence of cancer in Kentucky. Additionally, Kentucky is attempting to create a medical research "hub" by providing funds for this increased medical research.

In the area of medical privacy, Kentucky does not generally recognize the physician patient privilege, although physicians are ethically bound to protect patient confidences. There are various mental health care privileges recognized in Kentucky law as well as privacy provisions regarding specific diseases such as HIV/AIDS and sexually transmitted diseases. A 1999 report from the Health Privacy Project at Georgetown University notes that Kentucky statutorily grants a patient the right of access to medical records in the possession of a health care provider or a hospital but does not have a general, comprehensive statute

prohibiting the disclosure of confidential medical information, and any privacy protections are addressed in statutes governing specific entities or medical conditions. There is no statute that generally grants the patient the right of access to his or her medical records, and health care providers generally consider these records to be the property of the provider. For example, under KRS 422.317, a patient has the right to one free copy of his or her medical record from a health care provider or hospital, and the hospital or health care provider may charge up to \$1 per page for additional copies. Private review agents are prohibited from disclosing confidential medical information without using procedures to protect patient confidentiality under KRS 311.139, but the statute allows the review agent to disclose patient information to third parties with which the agent is affiliated. Other provisions of medical privacy were part of 1998 House Bill 315, discussed below.

In the 1990's, Kentucky adopted extensive reforms in the health care system, which included health insurance reforms. These predated the national HIPAA law, which was not enacted until 1996, and they provided for many of the reforms later instituted nationally. In the 1994 and 1996 regular sessions of the General Assembly, the General Assembly passed legislation that prohibited certain types of underwriting practices in health insurance. Following the passage of the 1994 and 1996 bills, there were around 40 individual and small group health insurance carriers that stopped issuing health insurance in the state, citing increased costs and restrictions on business that were not in force in other states. The Governor called a special session in 1997 to address these health insurance issues, but no bill was passed as a result of that session.

98 House Bill 315 and Genetic Testing/Information

In the 1998 regular session of the General Assembly, House Bill 315 changed many of the provisions in the health care reform bills, and there were bills introduced, including Senate Bill 334, that concerned genetic testing and genetic information. 1998 Senate Bill 334, as introduced, dealt comprehensively with the subject of genetic testing in insurance, but this bill did not pass. The bill provided as follows:

- Defined the terms “genetic characteristic,” “genetic information,” and “genetic test”;
- Prohibited insurance companies offering individual health insurance or group health insurance from excluding any individual or eligible dependents or establishing any rate or terms on the basis of any genetic characteristic;
- Prohibited discrimination on the basis of genetic information or the refusal to submit to a genetic test in the issuance, renewal, or extension of a supplemental limited benefit health, credit life, credit accident, disability, annuity, or life insurance;
- Provided for informed consent to obtain genetic information and standards for retention of genetic information, with certain exceptions;
- Limited disclosure of genetic testing information;
- Provided for notice to the person upon whom the test was performed of the fact that the test was performed; and
- Provided penalties for violations.

The 1998 General Assembly passed House Bill 315, which repealed many of the provisions relating to rate restrictions on health insurance and guaranteed issuance of health insurance coverage. The bill was also designed to comply with the federal HIPAA provisions, which was enacted after the 1996 Kentucky law went into effect and provided an “acceptable alternative mechanism” for individual health coverage.

98 RS HB 315 also created a provision for a high risk pool for people unable to obtain health insurance due to high-cost conditions. Called the Guaranteed Access Program or GAP, it is intended to qualify as an acceptable alternative mechanism under the federal HIPAA law. If a person seeking individual health insurance is not “eligible” and has had a certain high-cost condition within three years of applying for coverage, he or she is eligible for a GAP plan.

The high-cost conditions covered are:

acquired immune deficiency syndrome (AIDS), angina pectoris, ascites, chemical dependency cirrhosis of the liver, coronary insufficiency, coronary occlusion, cystic fibrosis, Friedreich's ataxia, hemophilia, Hodgkin's disease, Huntington chorea, juvenile diabetes, leukemia, metastatic cancer, motor or sensory aphasia, multiple sclerosis, muscular dystrophy, myasthenia gravis, myotonia, open heart surgery, Parkinson's disease, polycystic kidney, psychotic disorders, quadriplegia, stroke, syringomyelia, and Wilson's disease.

In addition, the Commissioner of the Department of Insurance is authorized under the legislation to add other high-cost conditions to the list. Persons with these 28 listed illnesses may be charged up to 35 percent above the average rate for people with insurance, and 50 percent higher for those who did not have prior insurance coverage. Several of the listed conditions have specific genetic abnormalities as their basis, including cystic fibrosis, Friedreich's ataxia, hemophilia, Huntington's disease, multiple sclerosis, myasthenia gravis, myotonia, Parkinson's disease, polycystic kidney, and Wilson's disease. Additionally, some of the broader categories, such as metastatic cancer and open heart surgery, may encompass persons with genetically based diseases.

Additionally, the bill contained provisions that give some protections to people who have had genetic tests or have received genetic information, but these protections are limited by the fact that there are no definitions of key terms in the law. One provision relates to discrimination on the basis of genetic testing in group and individual health plans. This section is codified at KRS 304.12-085, and reads, in pertinent part:

(2) In the case of benefits consisting of medical care provided under, offered by, or in connection with a group or individual health benefit plan, the plan or insurer may not deny, cancel, or refuse to renew the benefits or coverage, or vary the premiums, terms, or conditions for the benefits or coverage, for any participant or beneficiary under the plan:

(a) On the basis of a genetic test, for which symptoms have not manifested; or

- (b) On the basis that the participant or beneficiary has requested or received genetic services.

This section makes no reference to “eligible individuals” and appears to refer broadly to benefits offered to any individual or group. However, if the symptoms of a disease have manifested themselves, then the person may be subject to denial or cancellation of benefits or to higher premiums.

Additionally, KRS 304.12-085(3) provides that health benefit plans or insurers offering disability income plans may not request or require applicants, participants, or beneficiaries to disclose to the plan or insurer any genetic test about the participant, beneficiary, or applicant. KRS 304.12-085(4) further provides that “a group or individual health benefit plan or insurer offering health insurance in connection with a health benefit plan may not disclose any genetic test about a participant or beneficiary without prior authorization by the participant. The authorization is required for each disclosure.” While KRS 304.12-085(5) provides definitions of the terms “health benefit plan” and “insurer,” by reference to other sections of KRS Chapter 304-17A¹, there are no definitions of “genetic test,” “genetic information,” or “genetic services.” The Department of Insurance has issued a regulation providing for definitions, and this regulation will be discussed below.

Another part of House Bill 315 provides for protections from exclusion on the basis of genetic information. KRS 304.17A-200 provides that an insurer that offers health benefit plan coverage in the small group, large group, or association market may not establish rules for eligibility of any individual to enroll under the terms of the plan based on a list of health status-related factors in relation to the individual or the dependent of the individual, and this list of health status related factors includes genetic information. This provision does not apply, however, to those people with individual insurance plans, so there is no prohibition against an insurer making an individual ineligible for coverage on the basis of genetic information that the insurer has received, provided it does not violate the provisions of KRS 304.12-085.

An additional provision of House Bill 315, KRS 304.17A-220(3), provides that genetic information cannot be treated as a pre-existing condition exclusion which would exclude coverage for the condition for a period of time in the absence of a diagnosis of the condition related to this information. This section only applies to group health plans and insurers and would not apply to individual health plans. However, KRS 304.17A-230(1) provides that health insurers offering individual coverage shall not impose any pre-existing conditions exclusions as to any “eligible” individual, and genetic information is not to be treated as a pre-existing condition in the absence of a diagnosis of the condition related to the information. An “eligible individual” is one who meets the criteria of KRS 304.17A-005(7).

¹ KRS 304.12-085(5) states, “[f]or purposes of this section, unless the context requires otherwise:

- (a) "Health benefit plan" has the meaning given it in KRS 304.17A-005; and
- (b) "Insurer" has the meaning given it in KRS 304.17A-005.”

Additionally, KRS 304.17A-230(2) provides that health insurers that impose pre-existing conditions limitations on individuals not meeting the definition of “eligible individual” have to comply with the pre-existing conditions limitation provisions of KRS 304.17A-220.

House Bill 315 also recognized a patient's right of privacy in the content of a patient's record and communications between a patient and a health care provider with regard to mental health or chemical dependency and provides that:

- (1) An insurer may request the provider to furnish the insurer only such limited information concerning the patient from a patient's record as is necessary for determining covered services and benefits, medical necessity, appropriateness, and quality of care for authorization or continuation of mental health and chemical dependency health services to be provided to the patient, or for payment for those services.
- (2) No third party to whom disclosure of patient records is made by a provider may re-disclose or otherwise reveal the mental health and chemical dependency records of a patient, beyond the purpose for which the disclosure was made, without first obtaining the patient's specific written consent to the re-disclosure.

(KRS 304.17A-555)

There is no general right of privacy in any other type of medical record, except for the specific genetic testing, screening, or information provisions discussed above.

Regulations Defining Statutory Terms

Since there is no definition of “genetic test” or “genetic information” in the law, the Department of Insurance promulgated administrative regulation 806 KAR 17:170E on July 1, 1998, which defined genetic information,” “genetic services,” and “genetic test.” In response to comments from associations of insurance companies and individual insurance companies, the Department changed some of the exclusions in the regulation. The original version of the emergency regulation also excluded from the definition of “genetic test” the following:

- routine physical examinations or routine tests performed as a part of a physical examination, chemical, blood or urine analysis;
- a test to determine drug use;
- a test for the presence of HIV;
- or any test commonly approved in clinical practice by the Federal Food and Drug Administration.

A subsequent version of the emergency regulation read that the definition of genetic test excluded:

- a laboratory test for the analysis of blood or body fluids that may be performed in the course of a routine physical examination, provided no attempt is made to extract genetic information; or

- a test as established above that is newly approved for use in clinical practice by the federal Food and Drug Administration

The emergency regulation was replaced by an ordinary regulation, 806 KAR 17:170, and defines the terms “genetic information,” “genetic services,” and “genetic test.” “Genetic information” is defined as “information derived from a genetic test.” “Genetic services” is defined as “medical services employed to gather genetic information.” “Genetic test” is defined as “a laboratory test of human DNA or RNA used to identify the presence or absence of inherited alterations in the DNA or RNA which cause predisposition to disease or illness.”

The current version of the regulation, which limits the definition to the laboratory test of human DNA or RNA, appears to be a narrow definition, according to an expert on genetic testing in insurance at Stanford University. He holds that opinion because a test of human DNA or RNA would not necessarily test the proteins contained in genes and would not prohibit use of information in family history or medical history. Also, he stated that the definition’s limitation to alterations “which cause predisposition to disease or illness” would appear to limit the protections to only those tests which look at pre-symptomatic conditions. Additionally, he stated that the definition of “genetic test” would exclude a test for sickle cell anemia, as this would usually be done by a means other than tests of DNA or RNA, by looking at red blood cells. Tests for other genetic conditions, such as an inherited predisposition to colorectal cancer and Alzheimer’s disease, are done through testing proteins rather than testing RNA or DNA, and this definition would exclude those types of tests from the protections of the law. Additionally, a family history for Huntington’s disease would not be considered to be a genetic test under the definition, so someone with this history would not be protected under the definition.

Additionally, since the definition of “genetic information” is limited to that information “derived from a genetic test,” it is similarly limited in scope. Unlike the definition as described by NCSL, which would include information about genes, gene products, or inherited traits that may derive from an individual or family member, the regulation would limit it to that information obtained from a genetic test. Similarly, the definition of “genetic services” would include only those medical services that gather “genetic information,” which is delimited by the definition of “genetic test,” and would exclude any genetic services that did not fall within the scope of a medical service that involved a test for DNA or RNA.

The comments on the regulation as promulgated state that the insurance companies interested in the regulation were concerned with the scope of the definitions involved and stated that a broad definition would limit the established practice of insurers, particularly life and disability insurers, of using medical tests to determine insurability. There were no comments received from individual consumers, consumer groups, nor health care providers.

Other Considerations

Another issue that may limit the effect of the anti-discrimination prohibitions in 98 RS HB 315 is that the General Assembly has made a policy decision in the area of health insurance to place many people with symptomatic genetic diseases into a high risk pool. The practical reality is that many people with symptomatic genetic diseases are required to pay more for their health insurance. Since the law institutionalizes different treatment of persons with some genetic disorders, it may create an incentive for insurance companies to try to classify people as having these diseases. Additionally, there is nothing in the law that precludes health insurance companies from charging more for persons with genetic diseases. Also, there are no provisions in the law that limit the use of genetic information in life insurance.

Survey of Health, Life, and Disability Insurers in Kentucky

Assessing the impact of genetic testing on life, health, and disability insurance in Kentucky is a difficult proposition. The extent to which genetic testing is an issue of concern among the general public has been fairly well documented in the country. There is little information available that is Kentucky-specific. Nationally, the National Association of Insurance Commissioners (NAIC) convened a Working Group on Genetic Testing, which found that while insurers generally do not use tests of genetic material because of the costs involved in such testing, insurers do use genetic information received through multiple sources.

In order to determine the extent of genetic testing by life, health, and disability insurers, a survey on the impact of genetic testing in life, health, and disability income insurance in Kentucky was sent to fifteen life, health, and disability income insurance companies doing business in the Commonwealth. Additionally, comments were solicited from two associations of life and health insurance companies. Eight responses were received, including one comment from one association of life insurers. The results of the survey suggest that most life, health, and disability insurers are not directing insureds to undergo genetic tests. The association of life insurers that provided comments stated that, to their knowledge, no insurer providing life, disability, or long term care insurance requires individuals to take a genetic test, as the term is defined in Kentucky regulations. Life and disability insurers, however, commonly use a medical history, which may contain information about genetic conditions or may disclose that a test has in fact been taken in the past. Additionally, life and disability insurers ask for family history, which might give an indication as to particular genetic conditions in one's family. Since life and disability insurers use the MIB database, if information about a genetic test is in that information, then the participating insurers have access to it. Of course, if a company did not use individual risk underwriting, then the value of any genetic information would be negligible. All life and disability insurers, from narrative responses to the survey, indicated that they were concerned that "traditional" forms of assessments for purposes of insurability, such as blood tests, might be considered to be genetic tests, and they stated that this would pose a severe problem for the industry. The association of life insurers stated that companies must have access to and use of relevant medical information to assess risk, and that a broad concept of a "genetic test" could encompass much information that is needed to do this. Additionally, the association provided information with regard to proposed confidentiality standards.

Type of Coverage Offered and Market Segment

The survey asked companies which type of insurance they offered in Kentucky: life, health, or disability. Eight companies responded. Five of the companies offer life insurance, five offer health insurance, and three offer disability insurance; some companies offer multiple products. Additionally, one company stated that it offers long term care insurance in the individual and small group markets, although this question was not asked.

The survey asked for the market segment in which the insurance was offered, either individual (1-2 people) or small group (2-50 people). Of the five life insurance companies, all offer individual coverage, and one additionally offers small group coverage. The life insurers reported approximately 106,000 covered lives in Kentucky.² Of the three companies offering disability coverage, 2 offer individual coverage, and one offers small group coverage. The disability insurers reported approximately 5,000 covered lives in Kentucky.³ Of the five companies offering health insurance coverage, 3 offer small group coverage and 2 offer individual coverage. The health insurance coverage for individual and small group plans was estimated by these insurers at a total of 916,000 covered lives in Kentucky.

Effect of Restrictive Regulations on Insurance Business

The survey asked what effect would laws or regulations prohibiting or restricting the use of genetic testing have on the companies' business in Kentucky. Three out of the five companies offering health insurance provided no answer to the question, while the fourth stated that there would be no significant impact. However, the life and disability insurers, the insurers stated that the impact would be pronounced. One company stated that there would be a "significant risk of anti-selection", which would make it hard to quantify risk, thus driving up premiums for all insureds and creating a "tenuous business climate." Another life and disability insurer stated that restriction of genetic testing would have an adverse impact on business, if laws and regulations were created to include tests that life and disability insurers currently use in the definition of genetic testing. The insurer stated:

For example, cholesterol (HDL, LDL) is commonly used to determine if an individual is at high risk for coronary artery disease. Cholesterol is certainly partly if not almost wholly determined by genetic inheritance. And it is a marker in many individuals for the future development of disease. This does not make cholesterol a "genetic test." Height and weight are also genetically determined to the same extent and are not genetic tests. Type II diabetes (formerly called adult onset diabetes) has a strong inheritance pattern (it runs in families). Blood glucose levels (sugar) are used to determine the risk and diagnosis of diabetes, but blood glucose levels are not genetic tests. It would adversely affect our business if the laws or regulations restrict the use of genetic tests and do not differentiate genetic test information in the medical records of an insurance applicant from genetic tests performed by an insurance company. We know of no genetic testing currently being performed by an insurance company.

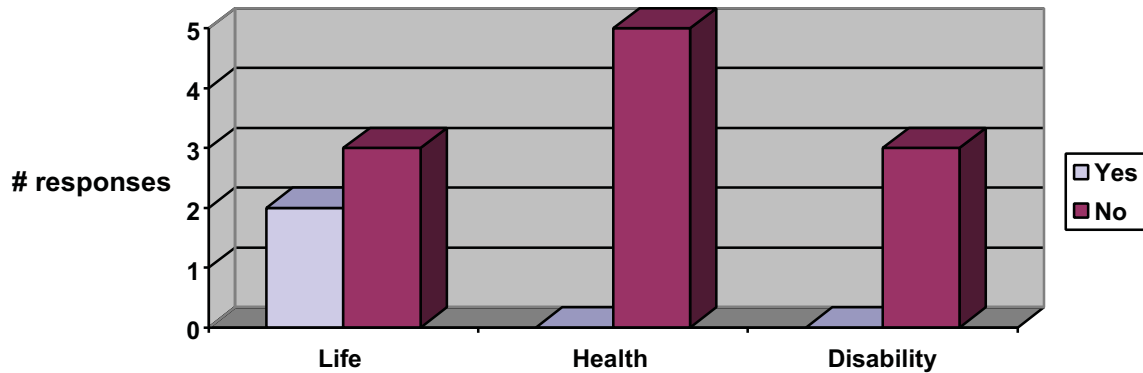
² Excluding one company, which reported 2.8 million covered persons, presumably throughout the United States.

³ Excluding one company, which reported 300,000 covered persons, presumably throughout the United States.

In response to the question, another life and disability company stated that the purpose of underwriting is to ensure that each person pays according to the risk posed to the company and other policyholders, and that prohibiting the use of genetic tests would undermine fairness in underwriting, as some people could withhold information. The company stated that this would allow some applicants to pay less for insurance than they should, forcing other policyholders to pay the difference. Another company felt that restricting access to genetic test information, if it becomes more commonly used and accepted in clinical practice, would affect the ability of insurers to classify risk, thus causing adverse selection and increasing the price of insurance overall.

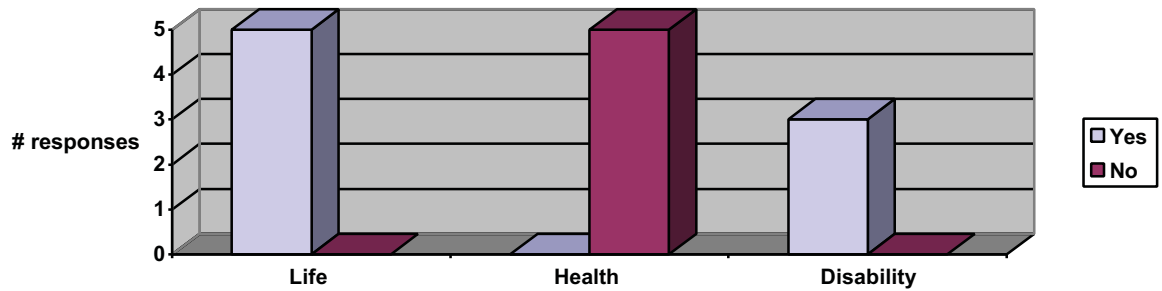
The companies were asked if they used individual underwriting of risk in Kentucky. Three health insurance companies said that they did use individual underwriting, and two did not. For the life and disability insurers, all use individual underwriting of risk.

Use of Predictors of Genetic Risk



None of the health or disability insurance companies said that they used predictors of genetic risk for Kentucky applicants. Two of the five life insurers, however, said that they use predictors of genetic risk for Kentucky applicants. One of those companies said that they use family history as a predictor of genetic risk, and the other company did not specify what method was used. Of the companies that stated they did not use predictors of genetic risk, two stated that they used family history and medical history.

Use of Family History



One health insurance company said it asked for information about family history from Kentucky applicants. All of the life and disability insurers said that they ask for information regarding family history.

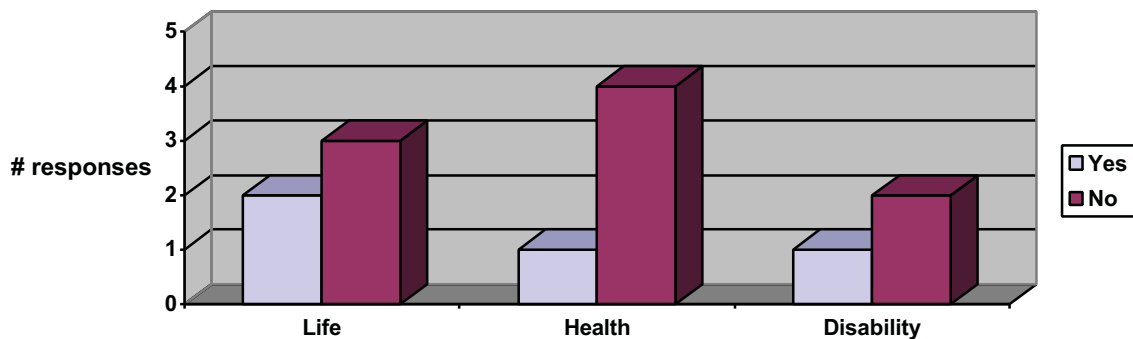
Request for Applicants/Insureds to Take Genetic Tests

No health, life, or disability insurance companies said that they ask Kentucky applicants or insureds to undergo genetic tests. One life and disability insurance company stated that while it did not order genetic tests on its applicants, it would expect that all information about any genetic tests that had been performed would be included in the applicant's medical record.

Requests About Carrier Tests

No health, life, or disability insurance company stated that it asked Kentucky applicants or insureds about carrier tests for recessive conditions where carriers were not affected by the condition.

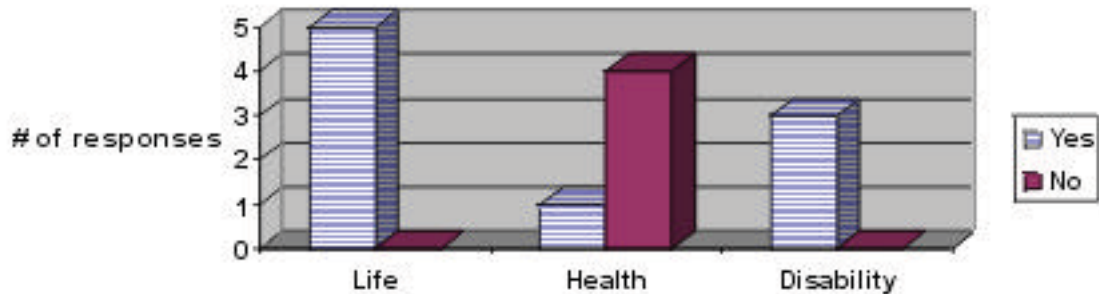
Distinguishing Between Methods of Genetic Testing



One health insurance company said that it distinguished between methods of genetic testing used when considering the result, if any were used, and the other four indicated that

no distinction was made. Two life insurance carriers stated that some genetic tests are included with medical records submitted as part of the underwriting process, and that these tests are reviewed by a medical director to determine the test's underwriting significance. Another company stated that it considers the methodology, validity, and predictive value of a genetic test, if it receives genetic test results. One disability insurance company stated that it distinguished between genetic testing methods.

Use of a Common Database



One company offering health insurance reported using a common database that is available to other insurers, while the other four did not. All of the life and disability companies reported using the Medical Information Bureau (MIB) database, which was discussed above. In addition, one company reported using state driving records, criminal records, and credit rating agencies.

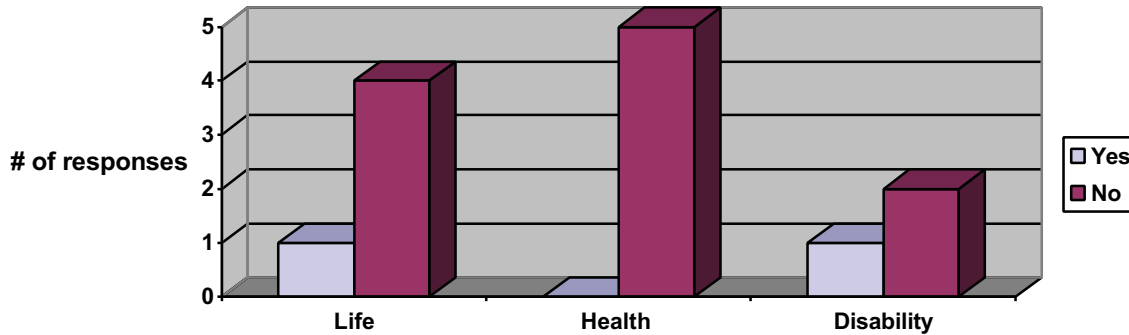
Confidentiality of Information

All companies reported that they keep information supplied to them by the applicant or applicant's provider confidential.

Use of Specialists

One of the health insurers reported relying on specialists to look at genetic information, if genetic testing information was used (the other four stated that the question was not applicable). Four of the five life and two of the three disability carriers reported using specialists to help interpret genetic information that was received, with one company reported retaining medical school faculty and genetic specialists to help interpret information that was received.

Rate Increases Based on Genetic Tests



No health insurer reported raising an individual's or group's rates on the basis of genetic information, and four of the five life and two of the three disability insurers reported that they did not change rates on the basis of such information. The company reporting that it might raise rates said that it did not order genetic tests, but that if it received a genetic test result, it would use it to increase or decrease the rate as would be appropriate.

Denial of Coverage and Applicant Notification

No company reported denying coverage to an individual or group in Kentucky on the basis of genetic tests or information. One health insurer stated that it would specifically notify Kentucky applicants or insureds that they were refused coverage or had premiums increased, while the other four stated that they do not so notify or that the question was not applicable. Two life insurance and two disability insurers stated that they specifically notified Kentucky applicants or insureds that they have been refused coverage or had their premiums increased on the basis of genetic test results, just as they would for any other denial or increase in premiums. The others stated that they had no denials or premium increases due to genetic test results.

Use of Internal Appeals Procedures

Two of the five health insurance companies reported that they had internal appeal procedures in case of a refusal of coverage or increased premium on the basis of genetic test results. Four of the five life insurers and all disability insurers reported that they had internal appeal procedures.

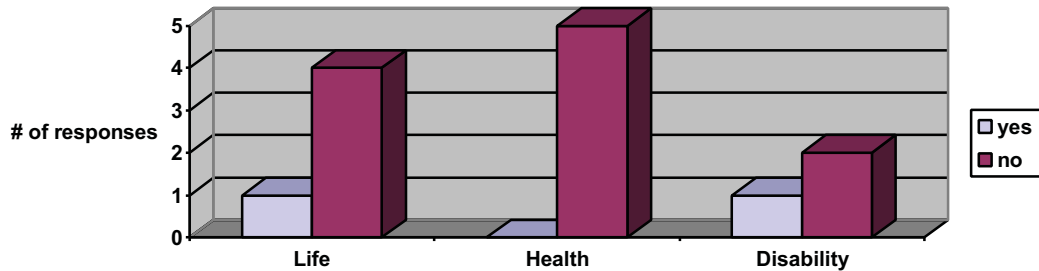
Concern About Adverse Selection

Two of the five health insurance companies and all of the life and disability companies stated that they felt that adverse selection would occur if the results of genetic tests were kept confidential.

Consideration of Non-Familial, Personal Predictors of Risk

All of the life and disability carriers and two of the health carriers stated that they take non-familial, personal predictors of risk into account when deciding to grant a policy (for example, cholesterol tests, blood pressure, etc.).

Questions Asked About Genetic Tests



Finally, no health insurers said that they ask or plan to ask any questions about genetic tests taken by applicants or applicants' family members, while one life and one disability insurer said that they ask or plan to ask about genetic tests.

Information From Providers and Consumers

Advocates of restricting insurance companies' access to genetic testing results believe that while genetic technology increases the ability to detect and prevent health disorders, it has already been misused to discriminate against or stigmatize individuals. In support of this, they cite several surveys. For example, a 1996 survey of individuals at risk of developing a genetic condition and parents of children with specific genetic conditions identified more than 200 cases of genetic discrimination among the 917 people who responded. The cases involved discrimination by insurance companies, employers, and other organizations that use genetic information. In another 1996 study of 332 members of genetic support groups, where the members had one or more of 101 different genetic disorders in their families, it was found that 25% of the respondents or affected family members believed they were refused life insurance, 22% believed they were refused health insurance, and 13% believed they were denied or let go from a job as a result of a genetic disorder. The study found that fear of genetic discrimination resulted in 9 percent of respondents or family members refusing to be tested for genetic conditions, 18 percent not revealing genetic information to insurers, and 17 percent not revealing information to employers.

The level of perceived or actual discrimination may point to the need for more information to determine the extent and scope of the problem. National experts have stated that it is difficult to estimate the extent to which persons may have been discriminated against in obtaining and keeping insurance on the basis of genetic testing or information, because it is generally difficult for the insured or potential insured to know the cause of the higher rate or other negative consequence. There is little information available in Kentucky

that documents the extent, if any, of consumer problems with genetic testing and insurance. One national researcher stated that much of the legislation in states regarding genetic testing is limited because the laws generally only address health insurance, and health insurers have little or no interest in predictive genetic test information or of family history of genetic disease, as their focus is on existing health problems. He stated that the laws may reassure geneticists and patients, but the laws may have unintended loopholes. Additionally, he stated that there may be very little actual genetic discrimination occurring, but it is difficult to assess this until test cases are brought to enforce these laws.

In order to provide additional information about the extent to which any problems with insurance have occurred in Kentucky, the Kentucky Department of Insurance was contacted to determine whether they have taken any enforcement actions on these issues. The Kentucky Department of Insurance conducted an in-house assessment to determine if any complaints had been registered with them regarding genetic testing. The Department determined that no complaints had been filed relating to genetic testing and insurance coverage. As noted above, there have been national studies that noted instances of discrimination against insureds on the basis of genetic testing or information, but the difficulty with such surveys is that, generally, insureds do not know why they have been turned down for coverage or why their rates have gone up, unless disclosures are made.

The medical and research community is of a varied opinion as to the extent of the problem with genetic testing in insurance. By way of background, the Code of Medical Ethics provides that with respect to insurance companies and genetic information:

Physicians should not participate in genetic testing by health insurance companies to predict a person's predisposition for disease. As a corollary, it may be necessary for physicians to maintain separate files for genetic testing results to ensure that the results are not sent to health insurance companies when requests for copies of patient medical records are fulfilled. Physicians who withhold testing results should inform insurance companies that when medical records are sent, genetic testing results are not included. This disclosure should occur with all patients, not just those who have undergone genetic testing.

The Kentucky Medical Association was not aware of any instances that their members had reported with respect to possible discrimination in insurance coverage. Individual health care providers in Kentucky that deal with genetic diseases, screening, and testing were contacted, and several reported that they had a difficult time getting health insurance carriers to pay for carrier testing for certain diseases, such as muscular dystrophy. Some reported that families undergoing genetic screening were generally concerned about confidentiality of the test results. However, others reported that they had not encountered problems with payment or instances of denial of insurance or increases in rates. One researcher in Kentucky stated that the research project he was involved in was careful to "wall off" any information from scrutiny from anyone external to the research. Additionally, one researcher working in the area of genetic testing in Kentucky stated that he had not received any complaints about insurance companies using the testing to discriminate against patients. He stated that genetic testing is used to identify the potential for adverse effects of

other therapies, and that it is doubtful that this type of testing could be used to discriminate. He also stated that genetic testing has become such a source of concern that its potential for doing good has been overshadowed by the perceived potential for discrimination and that the use of genetic testing could offer a great deal of therapeutic value for patients, could lower medical costs, and might prevent many long-term problems.

Additionally, professionals in the area of public health were interviewed. They stated that there is a perception that this information might be used against the individuals screened and their families, noting that the state lacks a comprehensive state plan relating to genetic services. They stated that a plan such as other states have developed might help coordinate efforts relating to these services, prevent discrimination or the potential for discrimination, and add to the data available to policymakers.

Since a formal survey was not done on the extent of discrimination against consumers or perceived discrimination in Kentucky, further exploration into this area may be needed in order to provide a full picture of the extent to which people may be affected by this issue in Kentucky, from the perspectives of providers, consumers, and their families. The General Assembly may wish to hold hearings before the committees of jurisdiction to receive testimony from affected individuals.

CHAPTER V

RECOMMENDATIONS

The key, it appears, to crafting a workable public policy on genetic testing is to look at both the narrow issue of its impact on insurance as well as the broader issues of genetics and medical privacy that may enter into the discussion. The General Assembly has several options available to it, should it choose to further legislate on this topic. The General Assembly has many policy choices to make that can only be made upon further discussion, examination, and resolution of the various competing forces at issue in the arena of genetic testing in insurance.

- 1. The General Assembly may wish to consider whether the definitions of “genetic testing,” “genetic information,” and related terms are sufficient.**

The definitions of “genetic testing” and “genetic information” and related terms are crucial. The General Assembly may wish to define the terms “genetic test” and “genetic information,” as these terms are not defined in the law, or it may wish to continue to allow the Department of Insurance to define these terms by administrative regulation.

- 2. The General Assembly may wish to monitor continuously other initiatives on genetic testing.**

The General Assembly may wish to request that the appropriate interim committee monitor the U.S. Congress’ actions on this subject, which may preempt any state laws that are passed relating to insurance. Additionally, it may wish to look at other states and study groups that are in the process of developing policies.

- 3. The General Assembly may wish to begin a public dialogue to complete the information available to the General Assembly and to determine the extent, if any, of discrimination on the basis of genetic testing or information in Kentucky.**

The General Assembly may wish to bring executive branch officials, insurance companies, health care providers, consumers and their families, and experts on genetics before its committees of jurisdiction to provide a public dialogue on the issue of genetic testing in insurance. Although there is a great deal of information available about genetic testing and insurance, it is not specific to Kentucky. It is difficult to obtain specific information that is relevant to Kentucky. Therefore, legislative testimony from Kentuckians who may have been affected by these issues, including insureds and health care providers, may be helpful to legislators in their attempt to set forth public policy on this rapidly changing issue.

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APPENDIX:
OTHER STATE LAWS ON GENETIC TESTING

ALABAMA	SB 113(1997), 27-5-13	Health Insurers, including self-insured	Prohibits health insurers from using genetic testing for a predisposition for cancer to determine insurability, rates, or benefits Prohibits insurers from denying coverage to applicant because he has been diagnosed with sickle-cell anemia.
ALASKA	21.54.100, 21.54.110	Group health	May not establish rules for eligibility based on genetic information; may not treat genetic information as a preexisting condition in absence of diagnosis
ARIZONA	20-448, 20-448.02	Life, Health, and Disability Insurers	Unfair trade practice to consider genetic condition in determining rates, terms, or conditions of life or health policy, to reject application for coverage based on genetic condition unless the applicant's medical history/condition/claims experience or actuarial projections establish that substantial differences in claims are likely to result from the genetic condition. Rejection of application for or determination of rates, terms, or conditions of a disability insurance contract on basis of genetic condition is unfair discrimination in the absence of a diagnosis of the condition relating to the testing information. Requires informed consent.

ARKANSAS	23-86-304, 23-86-306	Group health	May not establish rules for eligibility based on genetic information; may not treat genetic information as a preexisting condition in absence of diagnosis
CALIFORNIA	10140, 10146-10149.1, 10123.35, 742.20, 1374.7, 1374.9	Health, life and disability	Moratorium on genetic testing in health insurance until 2002. Health insurers shall not refuse to issue or sell policy or charge higher premium solely because person carries a gene associated with a disability in that person or the person's offspring. Extends disclosure requirements to self insured welfare benefit plan. Prevents health insurers from obtaining using, or maintaining any genetic information for any non-therapeutic purpose Provides minimum standards for underwriting in life and disability insurance plans. Provides penalties for negligent disclosure of genetic test results
COLORADO	10-3-1104.7	Health, group disability, long-term care insurance	Prohibits health and disability insurers from obtaining or using genetic information to deny health, group disability, or long-term care
CONNECTICUT	38a-816	Individual and group health insurance	Insurer cannot refuse to insure, or limit amount, extent, or kind of coverage available to an individual or charge individual a different rate for same coverage because of genetic information. Genetic information indicating predisposition to disease or condition is not a preexisting condition in the absence of a diagnosis of a disease or condition based on other medical information. Insurer may refuse to insure/apply preexisting condition limitation where the individual has exhibited symptoms of the disease or condition.

DELAWARE	23-18-2317, 19-710, 19-711	Health insurance	No discrimination against individual in issuance, denial, renewal of or fixing of rates, terms or conditions of insurance. Prevents disclosure of genetic information without consent, except in certain circumstances.
FLORIDA	760.40, 641.31073, 627.4301	Life and health insurance	No life or health insurer shall refuse to issue insurance policy solely because of sickle cell trait. HMOs offering group health insurance coverage may not establish rules of eligibility based on genetic information. Health insurers may not require or solicit genetic information, use genetic tests or consider a person's decisions or actions in regard to genetic testing for any insurance purpose. Requires informed consent for DNA analysis.
GEORGIA	33-54-1 to 33-54-8	Health insurance	Prohibits use of information obtained from genetic testing to deny access to health insurance. Prohibits use of genetic testing except to obtain information for therapeutic or diagnostic procedures & requires authorization and confidentiality protection.
HAWAII	431:10A, 432:1, 432D	Health insurance	Prohibits use of genetic information of individual or family member to deny or limit coverage. Prohibits disclosure of genetic information without written consent. Insurer cannot limit or deny coverage or establish eligibility continuation, enrollment, or premium payments based on genetic information.

IDAHO	19:5501-5518	-	Establishes DNA bank for persons guilty of certain sexual and violent crimes, prevents disclosure.
ILLINOIS	410 ILCS 513 215 ILCS 5/356v	Individual and group health insurers	Prohibits insurer from seeking genetic information for use in connection with policy. Insurer may consider test results if voluntarily submitted by insured and results are favorable to insured. Provides disclosure and confidentiality provisions.
INDIANA	16-39-5-2; 27-4-1-4; 27-8-5-26; 27-8-26; 27-13-7-14	Individual and Group Health insurers	Prohibits insurer from requiring test, from using information in an adverse manner, or inquiring into results. May consider test results if voluntarily submitted and results are favorable to insured.
KANSAS	40-2259, 22-2907	Life, disability, health, and long-term care insurance	Health insurers may not request or require genetic testing or require person to reveal that genetic testing has been performed, condition insurance on the fact that a test has been performed, or use test results in determining rates. For purposes of life, disability, and long-term care insurance, insurers may ask for the information or require a test, but shall not condition the provision of coverage on whether a test was performed, but may provide for rates reasonably related to the risk involved.
LOUISIANA	22:2002 22:213.6-7 22:1214 40:2207	Health insurance	Prohibits insurer from terminating insurance or discriminating on basis of prenatal tests. Prohibits insurer from requesting or requiring a test. Prohibits insurer from using any genetic information concerning an individual or family member's request for genetic services or tests to reject, deny, limit, cancel, refuse to renew, increase the rates of,

		Life and health insurance	<p>or otherwise affect the policy. Provides confidentiality and property rights.</p> <p>Prohibits discrimination on basis of sickle-cell trait.</p>
MAINE	5-503; 24A-2159c; 24-42222-B	Life, health, disability, long-term care Insurance	<p>Prohibits discrimination on basis of genetic information or refusal to submit to genetic test in the issuance, withholding, renewal or rates for health insurance. For life, disability, and long-term care insurance, insurer must use the genetic test in manner reasonably related to anticipated claims experience. Prohibits use of genetic information as preexisting condition in individual and group health insurance in the absence of a diagnosis of the condition.</p>
MARYLAND	48A –223.1	Health and life insurance	<p>Prohibits health insurers' use of genetic information, or disclosure without prior written authorization. Prohibits use of genetic test or results of test to determine eligibility, premiums, or coverage. (from 10-1-96 to 9/30/02)</p> <p>Prohibits discrimination in rate, premium, or dividend differential in life and annuity contracts solely because policyholder has sickle-cell, thalassemia, hemoglobin C, Tay-Sachs, or any genetic trait that is harmless within itself, unless there is actuarial justification.</p>

MINNESOTA	72A.139	Health and life insurance	Prohibits requiring genetic test or consideration of test results in determining eligibility for health insurance. Life insurers should obtain informed consent before testing and should recommend counseling.
MISSOURI	595.105, 375.1303.	Health insurers	Prohibits insurers from requiring or requesting person or relative or person to provide genetic information, take genetic test, or inquiring whether a test was refused, or asking the result of a test. Insurer must receive consent to consider test information.
MONTANA	33-18-206	All lines of insurance	Prohibits insurers from rejecting coverage or determining rates based on a genetic condition, unless applicant's medical condition & history, & either claims experience or actuarial projections establish that substantial differences in claims are likely to result from the genetic condition. Prohibits insurers from requiring genetic testing. Establishes standards for collection use and disclosure of genetic information in issuing insurance.
NEBRASKA	44-787	Health insurance	Provides that individual and group health insurers cannot use genetic information to cancel a policy, or as a preexisting condition in the absence of a diagnosis.
NEVADA	689A	Health insurance	Insurers may not require individual to take genetic test or disclose whether he has taken a test, or base rates on fact that person has taken a test or test results.
NEW HAMPSHIRE	141-H:1-6	Health insurance	Insurer may not require genetic testing or condition provision of insurance on test results, and may not consider result in determination of rate.

NEW JERSEY	17B:30-12	<p>Limited benefit plans, life, annuity, disability, credit life, accident</p> <p>Individual and group health, medical service corporations</p>	<p>Insurer may not discriminate in the application of genetic test results or genetic information in the issuance, withholding, extension, or renewal of a policy. Insurer may require genetic test, but must notify the individual that test will be required and obtain written consent for testing.</p> <p>Prohibits insurer from excluding individual or establishing rates on the basis of an actual or expected health condition or on the basis of any health characteristic.</p>
NEW MEXICO	<p>Regulations</p> <p>H. 331 (1998)</p>	Managed care plan	<p>Prohibits requiring genetic test, taking into consideration results of test, inquiring into results, making adverse decisions based on test, developing or asking questions based on test, canceling or refusing policy, limiting benefits based on test results. May consider results if favorable.</p> <p>Prohibits discrimination by insurer against person or member of family on basis of genetic analysis, information, propensity, participating in genetic research or use of genetic services. Requires written consent for use of genetic information.</p>
NEW YORK	<p>2612</p> <p>79-1</p>	All lines of insurance	<p>Prohibits genetic test without written informed consent of applicant, and provides standards for information to include in consent form.</p> <p>Samples to be destroyed w/in 60 days after test. Test results are privileged and confidential.</p>

NORTH CAROLINA	58-58-25 58-3-215	Life insurance (sickle-cell trait, hemoglobin c) Group health insurance	Prohibits insurer from refusing to issue policy solely for reason that person has sickle-cell or hemoglobin c trait, prohibits raising rate because the person has the trait. Prohibits raising premium, refusal to issue policy because of any information about genes, gene products, or inherited characteristics about individual or family member.
OHIO	1742.42-.43 3901.491-.501	Health insurance	Prohibits consideration of information obtained from genetic testing in processing group or individual health insurance applications Cannot cancel, refuse to renew, limit benefits. Cannot require test or inquire as to results. (effective until 2004).
OREGON	746.135	Health insurance	Requires informed consent prior to DNA testing. Cannot use results to reject, limit, raise rates, or affect policy. Cannot use favorable test to induce purchase of policy.
RHODE ISLAND	27-18-49, 27-19-41, 27-20-36, 27-41-50	Health insurers	Cannot use genetic test or results to reject, limit, cancel, refuse to renew, or raise rates of health insurance policy. Cannot request or require test. Requires prior authorization for disclosure.
SOUTH CAROLINA	38-93-10, 20,30,40,50, 60 (SC S 535)	Health insurers	Cannot terminate, restrict, limit or apply conditions to coverage of an individual or restrict the sale to an individual; cancel or refuse to renew the coverage of an individual; exclude an individual from coverage; impose a waiting period; exclude coverage for certain benefits and services on the basis of genetic information, or establish differential in

			premium rates for coverage. Requires written authorization for disclosure of genetic information except under certain circumstances. Requires informed consent for testing.
TENNESSEE	HB 413 (1997)	Health insurance	May not cancel or deny coverage, vary conditions or premiums on basis of request or receipt of genetic services. Limits disclosure of information, requires written authorization for release.
TEXAS	Article 21.73	Group health insurance	May not use information to reject, deny, limit, cancel, refuse to renew or increase premiums. Provides access to test results.
VERMONT	20-113(4), 18-217, 80-4724	Insurance	Limits requiring individual to undergo DNA testing to criminal investigation, determination of parentage, identification of remains. Prohibits discrimination in insurance.
WISCONSIN	631.89	Life and health Insurers	Cannot require or request test or condition insurance coverage or health care benefits on performance or result; cannot change rates. Statute does not apply to life or income continuation insurance however, the same restrictions apply if they obtain the information. Insurers may not require or request a health care provider to reveal whether an individual or a member of the individual's family has obtained a genetic test or indicate the results of the test.

Sources: Health Policy Tracking Service, National Conference of State Legislatures, Council of State Governments.