



**REPORT ON GENETIC INFORMATION  
AND GENETIC TESTING:  
INSURANCE AND PERSONALIZED MEDICINE**

**DECEMBER 2009**

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## Executive Summary

The Health and Government Operations Committee in the House of Delegates and the Finance Committee in the Maryland Senate asked the Maryland Insurance Administration ("MIA") to convene a Workgroup on Genetic Testing to explore the use of genetic information and genetic testing in disability and life insurance as well as personalized medicine. This report summarizes the findings and recommendations of the MIA based on the information reviewed and considered by the Workgroup.

Public concerns and fears about genetic information and genetic testing have led states and the federal government to limit the use of genetic information and genetic tests, particularly in health insurance.

While all types of health and life insurance may be purchased on a group or an individual basis, most Americans receive health benefits through their employer and have come to expect health benefits to be a part of their compensation. Disability, long-term care and life insurance are more discretionary purchases, increasing the risk of information asymmetry and adverse selection.

Insurers use medical underwriting to lower the risk of information asymmetry and adverse selection. Currently, medical underwriting for disability, long-term care and life insurance relies on certain genetic information such as family history. Although DNA-based genetic tests are not used today in medical underwriting, insurers want to maintain the ability to use them in the future.

The Workgroup agreed to a set of principles to use to assess public policy options. The Workgroup applied these three principles to three public policy options: (1) prohibit the use of genetic tests for disability, long-term care and life insurance under a certain dollar threshold; (2) prohibit insurers from requiring a genetic test but allow insurers to consider a genetic test an individual has had as long as the genetic test has proven to accurately confirm a diagnosis or predict a future outcome; and (3) make no change in current law.

Although the Workgroup did not reach a consensus, the MIA recommends the General Assembly amend the statute to permit insurers to use genetic information when underwriting disability and life insurance but prohibit insurers from requiring an applicant to undergo a genetic test. This makes the standards for the use of genetic information and genetic tests uniform for disability, long-term care and life insurance but recognizes that this standard should not be the same as the national standard for health benefits because of the more voluntary, discretionary characteristics of the purchase of disability, long-term care and life insurance.

## Introduction

During the 2009 Maryland Legislative Session, the Maryland General Assembly considered five bills pertaining to genetic information and genetic testing in insurance and personalized medicine. Each is summarized below:

- House Bill 1/Senate Bill 2, "Disability Insurance – Discrimination Based on Genetic Information or Tests – Prohibited," would have prohibited an insurer from using genetic information to reject, deny, refuse to renew, or increase rates on a disability contract.
- House Bill 2/Senate Bill 1, "Life Insurance and Annuities – Genetic Tests, Information, and Services – Prohibited Acts," would have prohibited an insurer from requesting, requiring, or using the results of a genetic test when issuing an annuity risk insurance policy unless the insurer demonstrated it is actuarially justified.
- House Bill 11/Senate Bill 57, "Insurance – Violation of Genetic Nondiscrimination Laws – Private Cause of Action," would have provided individuals who are injured due to an insurer's violation of genetic discrimination laws with a private cause of action.
- House Bill 12/Senate Bill 54, "Genetic Privacy – Individual's Genetic Information – Personal Property Rights," would have required an individual's informed consent prior to administering a genetic test and made an individual's genetic information the exclusive property of the individual from whom the sample was collected.
- House Bill 445, "Maryland Health Care Commission – Personalized Medicine – Study," would have required the Maryland Health Care Commission (MHCC) to create a formal workgroup to study issues related to the implementation of personalized medicine, including analysis of the impact of the federal Genetic Information and Nondiscrimination Act ("GINA") on Maryland's regulation of personalized medicine.

None of these bills passed. Consequently, the House Health and Government Operations Committee and the Senate Finance Committee asked the Maryland Insurance Administration ("MIA") to convene a Workgroup on Genetic Testing ("Workgroup") to explore the topics below to further the committees' deliberations on genetic information and genetic testing, insurance and personalized medicine:

- Current state of genetic testing
- Availability of genetic tests
- Means of obtaining a genetic test
- Prevalence of genetic testing
- Anticipated outcome of genetic testing
- Role of genetic testing in long-term care insurance, disability insurance, and risk insurance

- Privacy considerations related to genetic testing
- Principles for public policy and the use of genetic testing
- Regulation of personalized medicine.

As requested by the Committees, the MIA invited the insurance industry, the Office of the Attorney General, the Department of Health and Mental Hygiene, Johns Hopkins University, and the University of Maryland to designate an individual to participate in the Workgroup. The sponsors of the 2009 legislation, Delegate Manno and Senator Forehand, were also invited to join the Workgroup. In addition, any other individual expressing interest in the Workgroup was allowed to participate.

The Workgroup held five meetings between June and October of 2009. Although the Workgroup agreed on some general principles to guide public policy discussions on the permitted use of genetic information and genetic testing in insurance underwriting and rating, no consensus was reached regarding the permitted use of genetic information and genetic testing in disability and life insurance.

The remainder of this report summarizes the information reviewed by the Workgroup, some of the views offered by Workgroup participants, and the MIA's conclusions based on these deliberations.

### Genetic Information and Genetic Testing

Genetic information is the heritable biological information coded in the nucleotide sequences of DNA or RNA. Family history and genetic tests are both sources of genetic information. Genetic tests include biochemical tests and DNA-based tests. Genetic tests:

- Confirm or rule out a known or suspected medical condition
- Predict development of a medical condition
- Determine if an individual is a carrier of a medical condition
- Determine if an embryo or fetus has a medical condition
- Determine if a newborn has a medical condition
- May be used in medical research

Today, over 1,000 genetic tests are available. While other states permit direct-to-consumer genetic testing, genetic tests in Maryland must be ordered by a physician and, except for research purposes, must be performed by a licensed laboratory. This helps to ensure the test's accuracy as well as patient understanding of the results. Despite Maryland's attempt to regulate the direct-to-consumer tests, Maryland residents can easily purchase tests on-line, thereby sidestepping Maryland's law. Accordingly, the insurance industry representatives in the Workgroup expressed great concern about the consequences of direct-to-consumer genetic testing, a method providing the consumer with information that may not be available to the insurer during underwriting, creating information asymmetry and adverse selection.

DNA-based genetic tests offer the promise of providing more genetic information and furthering our understanding of the relationship between genetics, the environment and health.

Such information may be used to improve medical practice, to help prevent a disease or condition, as well as to help tailor treatment for an individual thereby improving health outcomes. However, at this point in time, the use of DNA-based genetic testing in medicine is in its infancy.

Genetic research continues to identify mutations that are tightly linked to specific diseases, genetic variations that are associated with an increase in the risk for developing a disease and predicting responses to drugs. Because such research has the potential to significantly improve medical practice, it is important to address the public's fears about genetic tests and research. An educational campaign to improve the public's understanding of genetic information and genetic tests and existing protections against inappropriate uses of genetic information and genetic tests by insurers could help to ameliorate these fears and help gain further support for this important research.

### Health and Life Insurance

Health insurance is defined under Maryland law as insurance of human beings against bodily injury, disablement, and expenses incurred in prevention of sickness or dental care. Health insurance includes major medical insurance (health benefits) and vision, dental, disability, long-term care, fixed indemnity, specified disease, Medicare supplemental, accidental death and accidental dismemberment insurance.

In Maryland, health insurance may be sold by licensed health insurers, property and casualty insurers, or life insurers with health authority. Most health insurance is sold by health insurers and nonprofit health service plans (\$6.7 billion in premium in 2008 in Maryland) or life insurers (\$2.4 billion in premium in 2008 in Maryland). Health benefits account for about 70 percent of all health insurance written premium.

Life insurance is defined under Maryland law as insurance for which the probabilities of the duration of human life or the rate of mortality are an element or condition of the insurance. Life insurance includes term life, whole life, variable life, universal life, universal variable life, and endowment benefits.

In Maryland, life insurance may only be sold by licensed life insurers. In 2008, there were 394 licensed life insurers who wrote \$2.6 billion in premium in Maryland.

The Workgroup focused on disability, long-term care and life insurance. In part, this was because federal and state law prohibit the use of genetic information in underwriting health benefits.

The insurance industry maintains there are important differences between the three types of insurance studied by the workgroup, and health benefits. According to the insurance industry, health benefits provide the financial ability to access health care by reimbursing health care providers, hospitals, pharmacies, and others the cost of an individual's health care whereas the benefits paid by disability, long term care and life insurance provide financial protection so that people facing serious illnesses or accidents can meet day-to-day financial obligations.

While all types of health and life insurance may be purchased on a group or an individual basis, most Americans receive health benefits through their employer and have come to expect health benefits to be a part of their compensation. Disability, long-term care and life insurance are more discretionary purchases.<sup>1</sup>

If an individual's demand for insurance is positively correlated with the individual's risk of loss and the insurer is unable to allow for this correlation in the price of insurance, adverse selection occurs. Adverse selection may occur because the individual has more information about his or her health than the insurer. This difference in information is referred to as information asymmetry.

Information asymmetry is of particular concern to insurers in the individual market where the individual determines when to purchase insurance and at what amount. If the insurer is not able to accurately assess the individual's risk and charge a premium commensurate with this risk, the financial consequences to the insurer may be devastating. The financial consequences are heightened in insurance lines such as disability, long-term care and life insurance where the policy may be in existence for a long time (e.g., 30 or more years), is guaranteed renewable, and future premium increases may not be based on a change in the individual's health condition or claims experience.

Underwriting is the tool insurers use to minimize information asymmetry and its outcome, adverse selection. Underwriting may include a number of areas (e.g., financial), but for the purposes of exploring the use of genetic information in life and health insurance only medical underwriting is relevant.

Medical underwriting in life insurance involves an analysis of the individual applicant's mortality risk. Medical underwriting in disability and long-term care insurance involves an analysis of the individual applicant's mortality and morbidity risk. An assessment is made for the individual applicant's known and unknown diseases or conditions. Highly trained professionals with backgrounds in statistics, medicine and science develop the medical underwriting tools used in disability, long-term care and life insurance.

Currently, medical underwriting for disability, long-term care and life insurance relies on certain genetic information such as family history. But DNA-based genetic tests are not used today in medical underwriting.<sup>2</sup>

### Personalized Medicine

Personalized medicine is a term that is used to describe medical practice based on an individual's genomic information. The term is a misnomer, however, since medical practice has

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<sup>1</sup> It should be noted that employers may be able to make disability, long-term care and life insurance available to their employees at a lower premium than employees could purchase on their own.

<sup>2</sup> The industry notes as medical science advances there is likely to be a point in the near future when genetic tests will be as common, predictive and accepted as cholesterol and other tests.

always been personalized. Physicians assess patients based on medical history, family history, physical examination, and laboratory tests. Based on this information, the physician determines the risk for a disease, how a disease will progress and the treatment plan.

Genomic information may improve medical practice, making it more personalized in three ways:

- Identifying mutations tightly linked to specific diseases
- Identifying genetic variations associated with an increase in the risk for developing a disease
- Predicting an individual's response to a drug to tailor therapy.

Today, there are DNA-based genetic tests and non-DNA based genetic tests that allow physicians to identify mutations tightly linked to specific diseases. In these cases, it is known the individual will develop the specific disease. Examples include sickle-cell anemia, cystic fibrosis, hemophilia, and Huntington's disease.

While there are DNA-based genetic tests that have identified genetic variations associated with an increase in the risk for developing a disease, the link between the genetic variation and the environment has not been well established. Thus, the results of such tests are insufficient to make decisions regarding prophylactic measures or life expectancy.

Similarly, the link between a genetic variant and a response to a given drug has been shown for certain diseases, such as asthma, heart failure, hypertension and diabetes. However, a high degree of predictive value has yet to be achieved.

Achieving the promise of personalized medicine requires more genetic research. Maintaining a legal and regulatory environment supportive of genetic research is important in attracting physicians and scientists interested in this field to Maryland. Assisting genetic research may be enhanced by permitting hospitals to collect genetic samples from all admitted patients as has been done by other states.

### Genetic Exceptionalism

If genetic information is qualitatively different from other forms of personal or medical information, then it stands to reason that it requires greater protection. This is known as genetic exceptionalism. Proponents of genetic exceptionalism point to three reasons why genetic information is different: it can predict disease occurrence in an individual and the individual's family members; it uniquely identifies a person; and it may be used to discriminate and stigmatize individuals. Others believe that genetic tests should not be treated differently than any other blood or fluid test.

The use of DNA-based genetic testing has heightened concerns about the use of genetic information. A 2006 survey found over 50 percent of respondents were concerned life and

health insurance companies would gain unauthorized access to personal genetic information.<sup>3</sup> Proponents of genetic exceptionalism point to such concerns as reason to enact state and federal law to give greater protections to genetic information.

As the previous section suggests, whether genetic information obtained from DNA-based genetic testing can predict disease occurrence in an individual may be more complicated than proponents of genetic exceptionalism maintain. Nonetheless, public concerns and fears about genetic information and genetic testing have led the states, the federal government and other nations to limit the use of genetic information and genetic tests in certain types of insurance.

### Genetic Information, Genetic Testing and Insurance: Statutory Limitations

Many states have prohibited the use of genetic information and genetic testing in underwriting for health benefits, a prohibition recently extended to all health benefits with the passage of GINA. Unlike health benefits, the debate about the use of genetic information and genetic tests in disability, long-term care and life insurance has focused primarily on genetic tests. This is because it is very difficult to define genetic information separately from health information. Genetic information includes family history, a history routinely explored and permitted for a very long time during medical underwriting for disability, long-term care and life insurance.

Only a few states have limited the use of genetic testing in underwriting for disability, long-term care and life insurance. (See Appendix 2 for a complete review of state laws.) In Maryland, for long-term care insurance, insurers may not require a genetic test to obtain a policy or to charge a different rate; however, insurers may use the results of a genetic test to deny a policy or charge a different rate if the use of the genetic test is based on sound actuarial principles. See *Insurance Article, § 18-120*.

Some states have gone further than Maryland in defining the responsibility of the insurer if a genetic test is to be used during medical underwriting by requiring:

- The insurer to pay the cost of the genetic test
- Notification to the applicant that a genetic test may be used
- Informed consent before the insurer may proceed with a genetic test

Only two states (Alaska and Florida) have enacted statutes making genetic information a person's property. This definition has far-reaching implications for research, laboratories and clinicians, and both the MIA and the Workgroup concluded it was beyond the scope of their expertise to effectively evaluate the pro's and con's of defining genetic information as a person's property. As current state law and GINA demonstrate, it is not necessary to define genetic information as property in order to define the permissible use of genetic information and genetic tests in medical underwriting.

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<sup>3</sup> See Alissa Johnson, "Plunging into the Gene Pool," *NCSL*, March 2007.

Some European nations have taken other steps to limit the use of genetic tests in medical underwriting. In the Netherlands, for example, life insurers may not use previous genetic tests during medical underwriting for policies below a certain predetermined amount when the policies are bought as a mandatory purchase to obtain a mortgage. In some countries, the life insurance industry has entered into a formal moratorium agreeing not to require an applicant to undergo genetic testing.

### Public Policy Principles and Public Policy Options

The Workgroup agreed the following principles should be used to assess public policy options pertaining to the use of genetic testing in underwriting for disability, long-term care and life insurance:

- Minimize barriers to participate in genomic research
- Allow individuals to make their own decisions regarding whether to undergo genetic testing
- Promote fair underwriting and pricing decisions, balancing consumer and industry views of fairness
- Minimize/deter adverse selection
- Minimize genetic exceptionalism
- Anticipate scientific advancement
- Minimize regulatory complexity

Although the Workgroup successfully came to consensus on principles for public policy, the Workgroup did not reach consensus on the three public policy options in great detail:

- Prohibit the use of genetic tests for disability, long-term care and life insurance under a certain dollar threshold ("Option 1")
- Prohibit insurers from requiring a genetic test but allow insurers to consider a genetic test an individual has had as long as the genetic test has proven to accurately confirm a diagnosis or predict a future outcome ("Option 2")
- Make no change in current law ("Option 3")

A number of individuals participating in the Workgroup emphasized that genetic tests are different and, while we may minimize genetic exceptionalism, we cannot ignore it. There are social and psychological implications for an individual undergoing a genetic test and the individual needs to be prepared for these prior to taking a genetic test. The results of a genetic test have implications for the individual and for family members. There is a public fear of discrimination because we do not know the implications of our genetic make-up for all conditions.

Concerns were also expressed about a bias created by genetic discovery. Currently, there are diseases whose genes are known, and the testing provides a highly predictive outcome. There are other diseases whose genes are unknown, and there is very little accurate predictive testing available. Consumer rating would be skewed on the basis that those who are unlucky enough to have a known disease would be rated higher according to genetic testing. Those

individuals who carry the gene for a relatively unknown disease would face a better rating scheme.

The insurance industry countered that this scenario exists with respect to diseases where a diagnostic test may not be considered a genetic test and known disease may result in a higher rating, versus rating for an individual in whom the disease has not yet been diagnosed. Avoiding asymmetric information and potential anti-selection requires an insurer to price for known risk using all available information. In order to properly price an insurance product and accurately assess an insurance applicant to meet the anticipated experience, the insurer needs to know the potential risk of that applicant.

Option 1, based on the European experience, was viewed by some Workgroup participants as striking an appropriate balance between consumers and insurers. It gives all consumers access to some defined minimum insurance level, irrespective of their health or genetic make-up. But it does increase the risk of adverse selection, requiring mechanisms to spread the risk among insurers to ensure none has experienced greater adverse selection than others. It also requires a common definition of a minimum threshold. Most importantly, it requires an infrastructure to ensure consumers do not take advantage of this prohibition by simply buying several basic policies from multiple insurers.

Option 3 is favored by the insurance industry. They note there may be scientific advances in the area of genetics and they should not be precluded from using advances that more accurately predict risks, particularly if individual applicants have this information available to them and the insurer does not thus resulting in greater adverse selection. For others, this option does little to address consumer concerns about genetic tests and insurance, a concern that may make it more difficult to achieve the advances promised by a greater understanding of genetics and medicine.<sup>4</sup>

Option 2 offers additional consumer protections for disability and life insurance. It is similar to current Maryland law for long-term care insurance. It allows individuals to make the decision about whether to undergo genetic testing, and it allows insurers to use the results of genetic tests only if the genetic test has proven valid and predictive.

Based on the information reviewed by the Workgroup and the discussion of these three options, the MIA recommends the Committees consider Option 2. The MIA has provided suggested draft language should the Committees wish to consider this option during the 2010 Legislative Session. (See Appendix 5.) This draft language makes the standards for the use of genetic tests uniform for disability, long-term care and life insurance but recognizes that this standard should not be the same as the national standard for health benefits because of the more voluntary, discretionary characteristics of the purchase of disability, long-term care and life insurance. The industry objects to this approach and its views are included in Appendix 6.

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<sup>4</sup> According to the industry, asymmetry of information may occur because of direct-to-consumer marketing of tests or the lack of comprehensive communication between physicians which prevents medical records from always being complete.

**Appendix 1: Legislative Request for Workgroup**

Appendix 1: Legislative request for Workgroup

PETER A. HAMMEN  
46th Legislative District  
Baltimore City

Chair  
Health and Government  
Operations Committee



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February 11, 2009

Mr. Ralph S. Tyler, Esq.  
Maryland Insurance Commissioner  
525 St. Paul Place  
Baltimore, MD 21202

Dear Commissioner Tyler:

I am writing to request that the Maryland Insurance Administration convene a work group on genetic testing. As you know, four bills have been introduced during the 2009 legislative session related to genetic testing: HB 1- Disability Insurance - Discrimination Based on Genetic Information or Tests - Prohibited, HB 2- Life Insurance and Annuities - Genetic Tests, Information, and Services - Prohibited Acts, HB 11- Insurance - Violation of Genetic Nondiscrimination Laws - Private Cause of Action, and HB 12- Genetic Privacy - Individual's Genetic Information - Personal Property Rights. Each bill raises different questions about the role of genetic testing, its relationship to insurance, and the privacy of health information. In order for the General Assembly to better understand these issues, I believe a work group during the interim would be beneficial.

I am hopeful that the Administration will take the lead in convening the work group. I would like the work group to provide the General Assembly with information about the current state of genetic testing, the availability of genetic tests, the means of obtaining a genetic test (laboratory, Dr. office, internet), prevalence of genetic testing, the anticipated future of genetic testing, the role of genetic testing in long term care, disability and life insurance, privacy considerations related to genetic testing and principles for public policy on the use of genetic testing. Please include on the work group, at a minimum, representatives of the insurance industry, the Office of the Attorney General, the Department of Health and Mental Hygiene, the Genetics and Public Policy Center at Johns Hopkins University, and the Law and Health Care Program of the University of Maryland - School of Law. Please also include Delegate Manno or his designee and Senator Forehand or her designee.

Please let me know if you will be able to convene this work group. Thank you in advance for your assistance and leadership on this matter.

Sincerely,

Handwritten signature of Peter A. Hammen.  
Peter A. Hammen, Chairman  
Health and Government Operations Committee

PETER A. HAMMEN  
46th Legislative District  
Baltimore City

Chair  
Health and Government  
Operations Committee



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February 20, 2009

Mr. Ralph S. Tyler, Esq.  
Commissioner, Maryland Insurance Administration  
525 St. Paul Place  
Baltimore, MD 21202

Dear Commissioner Tyler:

Thank you for your letter dated February 13, 2009 confirming the Maryland Insurance Administration's establishment of a workgroup on genetic testing. The Health and Government Operations Committee looks forward to your report prior to the 2010 session.

Since the Committee's initial request for a workgroup, the Committee heard House Bill 445 - *Maryland Health Care Commission - Personalized Medicine - Study*. The bill raises issues similar to those raised by the genetic testing bills which prompted the Committee to request the workgroup. As a result, the Committee would like for the workgroup to examine the impact of the Genetic Information Nondiscrimination Act on the State's regulation of personalized medicine and to consider the permissible use of genetic information in underwriting life or disability insurance policies and the impact on personalized medicine.

Thank you again for your time and attention to this request. If you have any questions, please do not hesitate to contact me.

Sincerely,

Peter A. Hammen, Chairman  
Health and Government Operations Committee

cc: The Honorable Sheila E. Hixson, Delegate, District 20

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**Appendix 2: American Council of Life Insurers (“ACLI”) Survey**

ACLI LAW SURVEY  
Genetic Testing: Underwriting Limitations Based on  
Tests and Information

**What's New?**

Substantive changes in the survey are highlighted in **bold** and may reflect:

- Amendments to existing laws and regulations;
- New laws and regulations; or
- Expansion of the scope of the survey or additional information on the topic.

Multi-state compilation includes laws and regulations that prohibit life, long-term care, and disability income insurers from denying, canceling, refusing to renew, or otherwise conditioning insurance coverage, benefits or rates on the basis of genetic tests, genetic characteristics or genetic information. Provisions prohibiting underwriting based on a single specific genetic trait are also included.

Note that genetic testing/information laws that apply to health insurers but that exclude long-term care/disability income insurance are no longer included in this compilation. Likewise, laws specifically applicable to hospital, medical, and surgical benefits are not included. However, health insurance laws that provide no clear exclusion of long-term care/disability income insurance and laws in which the exclusion is ambiguous are cited herein. Please refer to ACLI's [Risk Classification Compliance Service](#) for the text of genetic testing laws and regulations.

Provisions that require insurers to maintain the confidentiality of genetic information and to obtain authorization for the release of such information are not covered by this survey but are cited in ACLI's *Law Survey* on [Privacy and Confidentiality Requirements](#).

ACLI *Law Surveys* contain live links to the Westlaw data base where you'll be able to view the text of the laws, regulations, and bulletins cited in the surveys. This feature, free to ACLI members, enables you to explore the topic further and to keep current with any changes until the survey's summaries are updated next year. Just click on a citation link and a window will open with text from the Westlaw data base. Note that you will be asked to sign off on a user agreement the first time you access the Westlaw data base.

The ACLI hopes this compilation is helpful as a quick reference for your questions on genetic testing. This survey does not constitute a legal opinion or conclusion by ACLI, its staff, or its member companies and should not be used as the sole basis for making individual company decisions or conclusions. The *Law Surveys* are reviewed and updated annually. Users are encouraged to refer to the text of the statutes and regulations cited for the most current and complete information.

Emily Wolf  
March 2009

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
Alabama <u>Ala. Code</u> <u>§ 27-5-13</u>	Health and disability Insurers may not deny coverage on the basis of sickle-cell anemia diagnosis.	Health and disability	
Alaska <u>Alaska Stat.</u> <u>§ 18.13.010,</u> <u>Alaska Stat.</u> <u>§ 18.13.100</u>	Informed and written consent needed for DNA collection, analysis, retention, disclosure. <u>Alaska Stat. § 18.13.010</u>	General applicability — not specific to insurers.	Definitions of "DNA," "DNA analysis," and "genetic characteristic" <u>Alaska Stat. § 18.13.100</u>
Arizona <u>Ariz. Rev. Stat. Ann. § 20-448,</u> <u>Ariz. Rev. Stat. Ann. § 20-448.02</u>	Insurers may not refuse to consider an application for life or disability insurance on basis of genetic condition. <u>Ariz. Rev. Stat. Ann. § 20-448(D)</u>  Rejection of application or determining rates, terms or conditions of insurance contract on basis of genetic condition. <u>Ariz. Rev. Stat. Ann. § 20-448(E)</u>  A diagnosis of a genetic condition is required for disability insurance underwriting actions that are based on a genetic test. <u>Ariz. Rev. Stat. Ann. § 20-448(F)</u>  Specific written informed consent required for genetic testing. <u>Ariz. Rev. Stat. Ann. § 20-448.02(A)</u>	Life and disability  [Under Arizona law, "disability insurance" includes medical expense insurance, disability income insurance, and long-term care insurance.]	Definitions of "gene products" <u>Ariz. Rev. Stat. Ann. § 20-448(L)(4), Ariz. Rev. Stat. Ann. § 20-448.02(B)(1)</u>  Definition of "genetic condition" <u>Ariz. Rev. Stat. Ann. § 20-448(L)(5)</u>  Definitions of "genetic test" <u>Ariz. Rev. Stat. Ann. § 20-448(L)(6), Ariz. Rev. Stat. Ann. § 20-448.02(B)(2)</u>
Arizona <u>Ariz. Rev. Stat. Ann. § 20-1379</u>	A genetic condition is not a preexisting condition in the absence of a diagnosis. <u>Ariz. Rev. Stat. Ann. § 20-1379(U)(15)</u>	Health care insurer (includes disability insurer, group disability insurer, blanket disability insurer).	Definition of "genetic information" <u>Ariz. Rev. Stat. Ann. § 20-1379(U)(6)</u>  Definition of "health status-related factor" <u>Ariz. Rev. Stat. Ann. § 20-1379(U)(8)</u>  Definition of "preexisting condition" <u>Ariz. Rev. Stat. Ann. § 20-1379(U)(15)</u>
Arkansas  No applicable provisions.			
California <u>Cal. Ins. Code</u> <u>§ 10146 et seq.</u>	Written informed consent is required for genetic testing. Life or disability income insurers requiring genetic tests must pay for the test. <u>Cal. Ins. Code § 10148(a)</u>  Life and disability insurers may not require genetic characteristic tests that may be used for determining eligibility certain coverage. <u>Cal. Ins. Code § 10149(b)</u>	Life and disability income	Definition of "genetic characteristics" <u>Cal. Ins. Code § 10147(b)</u>

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
California <u>Cal. Ins. Code</u> <u>§ 10143(a)</u>	Refusal to issue, sell or renew any policy, or otherwise condition rates or benefits based on applicant's genetic characteristics such as Tay Sachs trait, sickle cell trait, thalassemia trait and X-linked hemophilia A.	Life and disability Income	
Colorado <u>Colo. Rev. Stat. Ann.</u> <u>§ 10-3-1104.7</u>	Proper use of genetic testing information. <u>Colo. Rev. Stat. Ann. § 10-3-1104.7(3)(b)</u>  Specific, written, informed consent required. <u>Colo. Rev. Stat. Ann. § 10-3-1104.7(10)(a)</u>	Health care insurance, group disability, and long-term care	Definition of "genetic testing" <u>Colo. Rev. Stat. Ann. § 10-3-1104.7(2)(b)</u>
Connecticut <u>Conn. Gen. Stat. Ann. § 38a-816</u>	Under Unfair and Prohibited Practices Act, refusal to insure or continue to insure, limitation of coverage, or charging a different rate because of genetic information prohibited. <u>Conn. Gen. Stat. Ann. § 38a-816 (19)</u>	Health insurance (Includes long-term care and disability income)	Definition of "genetic information" <u>Conn. Gen. Stat. Ann. § 38a-816 (19)</u>
Delaware <u>Del. Code Ann. tit. 16 § 1220, Del. Code Ann. tit. 16 § 1221(a), Del. Code Ann. tit. 16 § 1224(a)(10)</u>	No person shall obtain genetic information about an individual without first obtaining informed consent from the individual. <u>Del. Code Ann. tit. 16 § 1221(a)</u>	General applicability — not specific to Insurers.	Definition of "genetic characteristic" <u>Del. Code Ann. tit. 16 § 1220(1)</u> Definition of "genetic information" <u>Del. Code Ann. tit. 16 § 1220(2)</u> Definition of "genetic test" <u>Del. Code Ann. tit. 16 § 1220(3)</u>
District of Columbia <u>D.C. Code Ann. § 2-1402.31</u> <u>D.C. Code Ann. § 2-1401.02</u>	Rules for eligibility, premium adjustments, and contribution amounts based genetic information prohibited. <u>D.C. Code Ann. § 2-1402.31 (3)</u>  Genetic test cannot be required. <u>D.C. Code Ann. § 2-1402.31 (4)</u>	Health insurer (does not specifically exclude long-term care, disability)	Definition of "genetic information" <u>D.C. Code Ann. § 2-1401.02 (12A-i)</u> Definition of "genetic test" <u>D.C. Code Ann. § 2-1401.02 (12B)</u>
Florida <u>Fla. Stat. Ann. § 626.9706, Fla. Stat. Ann. § 626.9707, Fla. Stat. Ann. § 760.40</u>	DNA analysis may be performed upon informed consent. <u>Fla. Stat. Ann. § 760.40(2)(a)</u>  Use of DNA analysis in decision to grant or deny insurance coverage. <u>Fla. Stat. Ann. § 760.40(3)</u>	General applicability, including Insurers	Definition of "DNA analysis" <u>Fla. Stat. Ann. § 760.40</u>

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
	Life and disability Insurers may not refuse to sell or charge higher rates because the Insured carries the sickle-cell trait. <u>Fla. Stat. Ann. § 626.9706, Fla. Stat. Ann. § 626.9707</u>	Life and disability	
Georgia No applicable provisions.			
Hawaii No applicable provisions.			
Idaho <u>Idaho Code § 39-8302, Idaho Code § 41-1313</u>	Discrimination based genetic test or private genetic Information prohibited. <u>Idaho Code § 41-1313.</u>	Life insurance, annuities and disability Insurance	Definition of "DNA" <u>Idaho Code § 39-8302(2)</u> Definition of "DNA sample" <u>Idaho Code § 39-8302(3)</u> Definition of "genetic analysis" or "genetic test" <u>Idaho Code § 39-8302(5)</u>
Illinois <u>410 ILCS 513/10, 410 ILCS 513/20</u>	Insurers may not seek Information derived from genetic testing for use in connection with policy of accident and health Insurance. Genetic testing Information may not be used for a "nontherapeutic purpose." <u>410 ILCS 513/20(a)</u>  Accident and health Insurers may only consider genetic test results if the individual voluntarily submits the results and the results are favorable to the Individual. <u>410 ILCS 513/20(b)</u>	Accident and health	Definitions of "genetic information," "genetic testing," and "genetic test" <u>410 ILCS 513/10</u>
Indiana <u>Ind. Code Ann. § 27-8-26-1 et seq.</u>	Insurer may not:  Require genetic test <u>Ind. Code Ann. § 27-8-26-5,</u>  Inquire about results of genetic test <u>Ind. Code Ann. § 27-8-26-6,</u>  Cancel or refuse to issue or renew coverage <u>Ind. Code Ann. § 27-8-26-7,</u>  Limit benefits or set premiums based on genetic <u>Ind. Code Ann. § 27-8-26-8</u>  When genetic test results may be considered <u>Ind. Code Ann. § 27-8-26-9</u>	Accident and sickness (life, disability income insurance specifically excluded)	Definition of "genetic screening or testing" <u>Ind. Code Ann. § 27-8-26-2</u>

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
Iowa No applicable provisions.			
Kansas <u>Kan. Stat. Ann. § 40-2259</u>	Use of genetic information in writing a type of insurance coverage other than life prohibited. Rates and coverage must be "reasonably related to the risk involved." <u>Kan. Stat. Ann. § 40-2259(d)</u>	Life, disability income, or long-term care	Definition of "genetic screening or testing" <u>Kan. Stat. Ann. § 40-2259(a)</u>
Kentucky <u>Ky. Rev. Stat. Ann. § 304.12-085; 806 Ky. Admin. Regs. 17:170</u>	Insurer offering disability income plan may not request or require disclosure of any genetic test about the participant, beneficiary, or applicant. <u>Ky. Rev. Stat. Ann. § 304.12-085(3)</u>	Disability income	Definitions of "genetic information" "genetic services," and "genetic test" <u>806 Ky. Admin. Regs. 17:170</u>
Louisiana <u>La. Rev. Stat. Ann. § 22:652.1</u>	Refusal of coverage or rate discrimination on the basis of a severe disability or sickle cell trait prohibited. <u>La. Rev. Stat. Ann. § 22:652.1(A), (D)</u>	Life, life annuity, and disability	
Maine <u>Me. Rev. Stat. Ann. tit. 24-A § 2159-C</u>	Unfair discrimination based on the application of genetic information or the results of a genetic test in the issuance, withholding, extension or renewal of certain insurance policies prohibited. <u>Me. Rev. Stat. Ann. tit. 24-A § 2159-C(3)</u>	Life, disability, long-term care, annuities, credit life and accident, and other specific policies	Definition of "genetic characteristic" <u>Me. Rev. Stat. Ann. tit. 24-A § 2159-C(1)(A)</u> Definition of "genetic information" <u>Me. Rev. Stat. Ann. tit. 24-A § 2159-C(1)(B)</u> Definition of "genetic test" <u>Me. Rev. Stat. Ann. tit. 24-A § 2159-C(1)(C)</u>

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
<p>Maryland <u>Md. Code Ann. Insurance § 27-208(a)(3)</u></p>	<p>Without actuarial justification, an Insurer may not refuse to insure or make or allow a differential in ratings, premium payments, or dividends in connection with life insurance and annuity contracts on basis of applicant or policyholder having sickle-cell trait, thalassemia-minor trait, hemoglobin C trait, Tay-Sachs trait, or a genetic trait harmless in itself. <u>Md. Code Ann. Insurance § 27-208(a)(3)</u></p> <p>For long-term care insurance: limitations on requesting a genetic test <u>Md. Code Ann. Insurance § 18-120 (B)(4)</u>; permissible use of genetic test results or genetic information <u>Md. Code Ann. Insurance § 18-120 (C)</u></p>	<p>Life and annuities, long-term care insurance</p>	<p>For long-term care insurance: Definition of "genetic information" <u>Md. Code Ann. Insurance § 18-120 (A)(2)</u> Definition of "genetic test" <u>Md. Code Ann. Insurance § 18-120 (A)(4)</u></p>
<p>Massachusetts <u>Mass. Gen. Laws Ann. ch. 175 § 120E</u></p>	<p>Refusal to issue or renew, charging an increased rate, and restrictions on coverage length based on genetic test results prohibited, with certain exceptions.</p> <p>An applicant cannot be required to undergo a genetic test as a condition to issue or renew policy.</p> <p>Standards for requesting genetic information on an application and the use of that information if the insured chooses to provide it.</p>	<p>Life</p>	<p>Definitions of "genetic information" and "genetic test"</p>
<p>Mass. Gen. Laws <u>Ann. ch. 175 § 108I</u></p>	<p>Subsection (b): unfair discrimination based on genetic test results prohibited; Insurers may not require a genetic test as a condition of issuance or renewal of policy.</p> <p>Subsection (c): Standards for requesting genetic information on an application and the use of that information if the insured chooses to provide it.</p>	<p>Disability/LTC</p>	<p>Subsection (a): definitions of "genetic information" and "genetic test"</p>

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
Michigan No applicable provisions.			
Minnesota <u>Minn. Stat. Ann. § 72A.139</u>	Written informed consent is required prior to testing to determine Insurability under policy of life insurance. <u>Minn. Stat. Ann. § 72A.139(4), (5), (6), (7)</u>	Life	Definition of "genetic test" <u>Minn. Stat. Ann. § 72A.139(2)(b)</u>
Mississippi No applicable provisions.			
Missouri No applicable provisions.			
Montana <u>Mont. Code Ann. § 33-18-206</u>	Refusal to consider application for, determine rates, or otherwise condition benefits on the basis of a genetic condition is unfair discrimination, with certain exceptions. <u>Mont. Code Ann. § 33-18-206(3), (4)</u>	Life and disability insurance	Definition of "genetic condition" <u>Mont. Code Ann. § 33-18-206(5)(c)</u>
Nebraska No applicable provisions.			

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
<p>Nevada <u>Nev. Rev. Stat. Ann. § 629.111</u>, <u>Nev. Rev. Stat. Ann. § 629.121</u>, <u>Nev. Rev. Stat. Ann. § 629.131</u>, <u>Nev. Rev. Stat. Ann. § 629.151</u></p>	<p>Cannot obtain any genetic information of a person without first obtaining the informed consent of the person or the person's legal guardian. <u>Nev. Rev. Stat. Ann. § 629.151</u></p>	<p>Insurers who provide coverage for long-term care and disability income excluded from applicability of chapter.</p>	<p>Definition of "genetic information" <u>Nev. Rev. Stat. Ann. § 629.111</u> Definition of "genetic test" <u>Nev. Rev. Stat. Ann. § 629.121</u></p>
<p>New Hampshire <u>N.H. Rev. Stat. Ann. § 141-H:1</u>, <u>N.H. Rev. Stat. Ann. § 141-H:5</u></p>	<p>Use of genetic information in writing a type of insurance coverage other than life, disability income, or long-term care insurance prohibited. <u>N.H. Rev. Stat. Ann. § 141-H:5</u></p>	<p>Life, disability income and long-term care insurance</p>	<p>Definition of "genetic testing" <u>N.H. Rev. Stat. Ann. § 141-H:1(IV)</u></p>
<p>New Jersey <u>N.J. Stat. Ann. § 17B:30-12</u></p>	<p>Unfair discrimination against an individual based on genetic test or genetic information in the issuance, withholding, extension or renewal of certain policies prohibited. Written informed consent prior to administration of a genetic test required if results will be used by insurer in issuing, withholding, extending or renewing life policy. <u>N.J. Stat. Ann. § 17B:30-12(f)</u></p>	<p>Life, health, credit life, annuities, and disability income insurance</p>	<p>Definitions of "genetic characteristic," "genetic information," and "genetic test" <u>N.J. Stat. Ann. § 17B:30-12(e)(2)</u></p>
<p>New Mexico <u>N.M. Stat. Ann. § 24-21-2</u> et seq,</p>	<p>Use genetic analysis, genetic propensity or genetic information in the ordinary conduct of business. <u>N.M. Stat. Ann. § 24-21-3(D)</u>, <u>N.M. Stat. Ann. § 24-21-4(C)</u>, <u>N.M. Stat. Ann. § 24-21-5(C)</u></p>	<p>Life, disability and long-term care insurance</p>	<p>Definitions of "DNA," "gene products," "genetic analysis," "genetic information," "genetic propensity," and "genetic testing" <u>N.M. Stat. Ann. § 24-21-2</u></p>
<p>New York <u>N.Y. Ins. § 2615</u>; <u>N.Y. Civ. Rights § 79-l</u></p>	<p>Written consent for genetic test and notification of adverse underwriting decision required. <u>N.Y. Ins. § 2615(a)</u> and (e)</p>	<p>Insurers</p>	<p>Definition of "genetic test" <u>N.Y. Civ. Rights § 79-l(1)(a)</u> "Genetic test" shall have the same meaning as defined in section [N.Y. Civ. Rights § 79-l] of the civil rights law." <u>N.Y. Ins. § 2615(l)</u> Definition of "genetic predisposition" <u>N.Y. Civ. Rights § 79-l(1)(b)</u></p>
<p>North Carolina <u>N.C. Gen. Stat. § 58-58-25</u></p>	<p>Refusal to issue a life policy or charging a high premium as a result of possession of the sickle cell trait or hemoglobin C trait is prohibited. <u>N.C. Gen. Stat. § 58-58-25</u></p>	<p>Life</p>	<p>Definition of "sickle cell trait" <u>N.C. Gen. Stat. § 58-58-25</u> Definition of "hemoglobin C trait" <u>N.C. Gen. Stat. § 58-58-25</u></p>

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
North Dakota No applicable provisions.			
Ohio <u>Ohio Rev. Code Ann. § 3901.49</u>	Prohibitions against requiring genetic screening or testing and allowable use of test results. <u>Ohio Rev. Code Ann. § 3901.49 (B)</u>	Sickness and accident insurance (specifically excludes disability income only, not long-term care)	Definitions of "genetic screening or testing," "insurer," and "sickness and accident insurance" <u>Ohio Rev. Code Ann. § 3901.49 (A)</u>
Oklahoma No applicable provisions.			
Oregon <u>Or. Rev. Stat. § 192.531, Or. Rev. Stat. § 192.535, and Or. Rev. Stat. § 746.135</u>  <u>Or. Admin. R. 836-051-0700</u>	Informed consent required prior to obtaining genetic information from an individual, or from an individual's DNA sample. <u>Or. Rev. Stat. § 192.535</u>  Proper use of genetic information. <u>Or. Rev. Stat. § 746.135</u>  Specific authorization required. <u>Or. Rev. Stat. § 746.135, Or. Admin. R. 836-051-0700</u>	Insurers	Definition of "genetic characteristic" <u>Or. Rev. Stat. § 192.531(10)</u> Definition of "genetic information" <u>Or. Rev. Stat. § 192.531(11)</u> Definition of "genetic test" <u>Or. Rev. Stat. § 192.531(14)</u>
Pennsylvania No applicable provisions.			
Puerto Rico No applicable provisions.			
Rhode Island No applicable provisions.			
South Carolina <u>S.C. Code Ann. § 38-71-860</u>  <u>S.C. Code Ann. § 38-93-10, S.C. Code Ann. § 38-93-40</u>	Group health insurers may not determine eligibility or charge higher premiums based on health status-related factors. <u>S.C. Code Ann. § 38-71-860(A)(1), (B)(1)</u>  Informed consent to genetic test required. <u>S.C. Code Ann. § 38-93-40</u>	Group health	Definition of "health status-related factor" <u>S.C. Code Ann. § 38-71-860(A)</u>  Definition of "genetic characteristic" <u>S.C. Code Ann. § 38-93-10(1)</u> Definition of "genetic information" <u>S.C. Code Ann. § 38-93-10(2)</u> Definition of "genetic test" <u>S.C. Code Ann. § 38-93-10(3)</u>

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
South Dakota No applicable provisions.			
Tennessee <u>Tenn. Code Ann. § 56-7-207</u>	Refusal to Issue or deliver any policy of life insurance based on possession of sickle cell trait or hemoglobin C trait prohibited. <u>Tenn. Code Ann. § 56-7-207(a)</u>	Life Insurance	Definition of "hemoglobin C trait" <u>Tenn. Code Ann. § 56-7-207(b)(1)</u> Definition of "sickle cell trait" <u>Tenn. Code Ann. § 56-7-207(b)(2)</u>
Texas <u>Tex. Ins. Code Ann. § 546.001 et seq.</u>	Genetic Information or a refusal to submit to genetic testing may not be used to deny, limit, cancel, nonrenew, or increase premiums policy premiums. <u>Tex. Ins. Code Ann. § 546.052</u>  Testing permitted under certain circumstances; use of results for inducement prohibited; genetic testing is allowed upon written consent. <u>Tex. Ins. Code Ann. § 546.051</u>  Genetic testing of a child in utero without the consent of the pregnant woman is prohibited; use of genetic information to coerce or compel a pregnant woman to have an induced abortion prohibited. <u>Tex. Ins. Code Ann. § 546.053</u>	Health benefit plans (Scope of article excludes disability income and long-term care policies, including a nursing home fixed indemnity policy, unless the commissioner determines that the policy provides benefit coverage so comprehensive that the policy is a health benefit plan.)	Definition of "DNA" <u>Tex. Ins. Code Ann. § 546.001(1)</u>  Definition of "genetic characteristic" <u>Tex. Ins. Code Ann. § 546.001(2)</u>  Definition of "genetic information" <u>Tex. Ins. Code Ann. § 546.001(3)</u>  Definition of "genetic test" <u>Tex. Ins. Code Ann. § 546.001(4)</u>  Definition of "RNA" <u>Tex. Ins. Code Ann. § 546.001(5)</u>
Utah <u>Utah Code Ann. § 26-45-102, Utah Code Ann. § 26-45-104</u>	Refusing to offer or renew, determination of premiums, coverage, cancellation, and any underwriting decisions based on private genetic information prohibited. Health insurers may not request or require a genetic test. <u>Utah Code Ann. § 26-45-104(1)</u>	Health care Insurance (excludes replacement of income)	Definition of "genetic analysis" or "genetic test" <u>Utah Code Ann. § 26-45-102(4)(a)</u>  Definition of "private genetic information" <u>Utah Code Ann. § 26-45-102(7)(a)</u>
Vermont <u>Vt. Stat. Ann. tit. 18 § 9331 et seq.</u>	Prior written authorization and informed consent required. <u>Vt. Stat. Ann. tit. 18 § 9332(d)</u>  Underwriting decisions or conditioning a policy on take a genetic test or the results of a genetic test prohibited. <u>Vt. Stat. Ann. tit. 18 § 9334(a)</u>	Life, health, disability, long-term care	Definition of "genetic information" <u>Vt. Stat. Ann. tit. 18 § 9331(6)</u>  Definition of "genetic testing" <u>Vt. Stat. Ann. tit. 18 § 9331(7)</u>

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
Vt. Stat. Ann. tit. 8 § 4724	Unfair methods of competition or unfair/deceptive acts (Includes the results of genetic testing. <u>Vt. Stat. Ann. tit. 18 § 9331(7)</u> , <u>Vt. Stat. Ann. tit. 8 § 4724</u> )	Insurer	
Virginia <u>Va. Code Ann. § 38.2-508.4</u> , <u>Va. Code Ann. § 38.2-3431</u> , <u>Va. Code Ann. § 38.2-3436</u>	Use of genetic information in sale and renewal of policies or determination of coverage prohibited. Discrimination in fees or commissions of agent/agency for enrollment/subscription or renewal based on genetic characteristics also prohibited. <u>Va. Code Ann. § 38.2-508.4(B)</u>  Genetic information shall not be treated as a preexisting condition in the absence of a diagnosis. <u>Va. Code Ann. § 38.2-3431(B)</u>  Health Insurers may not determine eligibility for coverage or charge higher premiums on the basis of health status-related factors. <u>Va. Code Ann. § 38.2-3436(A) (C)</u>	Accident and sickness (excluding disability income)	Definitions of "genetic characteristic," "genetic information," and "genetic test" <u>Va. Code Ann. § 38.2-508.4(A)</u>  Definition of "health status-related factor" includes genetic information. <u>Va. Code Ann. § 38.2-3431</u>  Definition of "preexisting condition exclusion" <u>Va. Code Ann. § 38.2-3431</u>
Washington  No applicable provisions.			
West Virginia  No applicable provisions.			
Wisconsin <u>Wis Stat. Ann. § 631.89</u>	Restrictions on use of result of genetic tests. <u>Wis Stat. Ann. § 631.89(3)</u>	Life or income continuation insurance	Definition of "genetic test" <u>Wis Stat. Ann. § 631.89(1)</u>
Wyoming <u>Wyo. Stat. Ann. § 26-19-107</u>	Genetic information, in the absence of a diagnosis of a condition related to the genetic information, may not be treated as a preexisting condition. <u>Wyo. Stat. Ann. § 26-19-107(f), (g)</u>  Restrictions on use of genetic testing information. <u>Wyo. Stat. Ann. § 26-19-107(m)</u>	Group disability	Definition of "health status related factor" <u>Wyo. Stat. Ann. § 26-19-107(o)</u>

**Appendix 3: Meeting Minutes**

## Workgroup on Genetic Testing

June 22, 2007  
Meeting Minutes

### Participants:

Paul Ballard	Riva Kinstlick	Robert Neill, Jr.
Miriam G. Blitzer, Ph.D.	Mary Kivlighan, J.D.	Susan Panny, M.D.
John Dodge, M.D.	Jennifer Kulynych, J.D., Ph.D.	Debbie Rivkin
Marta Harting	Honorable Roger Manno	Kimberly Robinson
Deborah Hellman, J.D.	Bruce Margolis, DO	Joan A. Scott, MS, CGC
Michael Hickey	Donna Meyer	Timothy Smith
May Jung, M.D.		

### Minutes:

The Workgroup on Genetic Testing held its first meeting to review and discuss the topics identified in Attachment 1.

In reviewing the work plan, a number of modifications were suggested. These included reviewing the legislative history of the restrictions on the use of genetic testing in Maryland law for health insurance and long-term care insurance; comparing the definitions of genetic testing in Maryland law with GINA; reviewing public opinion about people's fears regarding genetic testing; a presentation about the medical underwriting process used today by disability and life insurers; and input from the pharmaceutical and biotechnology industries to ascertain unintended consequences, if any, for restrictions on the use of genetic tests in insurance. The staff will incorporate these additional areas into the work plan.

The Workgroup then discussed the uses of genetic tests. An error was noted in the description for diagnostic testing. Genetic tests used for diagnostic purposes to confirm or rule out a known or suspected genetic disorder may be performed on symptomatic or asymptomatic individuals. Additional uses for genetic tests include research and prognostic (a genetic test to tailor treatment for an individual).

Genetic tests conducted for research may be performed for medical or non-medical uses and may be performed with or without consent. The results of genetic research tests may be identifiable or may be blinded. The results of genetic research testing may be provided to individuals or may not be provided. How the results of genetic tests are treated (e.g., personal medical information, property) may have an adverse effect on advancing research in the area of genetic testing.

The discussion pointed out that predictive testing offered to individuals with a family history or a genetic disorder alters the individual's view of the potential risk of disability or death and thus the proclivity to purchase one or both of these types of insurance. Insurers are concerned about the potential increased risk if individuals have more knowledge of their risk of disability or death than the insurer.

Next the Workgroup reviewed how genetic tests are ordered. While other states permit direct to consumer genetic testing, Maryland requires an order from a physician. This helps to ensure the accuracy of the information and to be sure the patient understands the results of the genetic test. Despite this prohibition, it is possible for a Maryland resident to order a genetic test directly from one of the 40 genetic testing companies.

The unique characteristics of genetic tests for research purposes were again pointed out. Research genetic testing may not be performed in a laboratory subject to CLIA regulations. In part, this is because research genetic tests do not necessarily have clinical relevance.

Regulated laboratories may only disclose medical information with the patient's consent. Because of this, the ability for an insurer to obtain the results of a genetic test ordered by a physician or directly by a consumer may be limited.

Questions arose from some members of the group regarding how health, life, and disability insurance were defined. The staff noted health insurance encompasses what consumers think of as health insurance as well as long-term care insurance and disability insurance. Next time the staff will provide an overview of insurance in order to alleviate further confusion.

## Workgroup on Genetic Testing

July 20, 2009  
Meeting Minutes

### Participants:

Paul Ballard	Jennifer Kulynych, J.D., Ph.D.	Debbie Rivkin
Miriam G. Blitzler, Ph.D.	Honorable Roger Manno	Kimberly Robinson
John Dodge, M.D.	Bruce Margolis, DO	Joan A. Scott, MS, CGC
Marta Harting	Donna Meyer	Timothy Smith
Michael Hickey	Susan Panny, M.D.	
Mary Kivlighan, J.D.		

### Minutes:

The Workgroup on Genetic Testing held its second meeting to review and discuss the types of insurance, legal protection of genetic information, state laws, and GINA.

The staff presented an overview of health and life insurance. Following a good deal of discussion, there appeared to be consensus that while health insurance is a varied line, not all health insurance is the same. The different statutory treatment of health benefits, disability and long-term care insurance suggests there is a consensus that while all are types of health insurance under Maryland law there are sound policy reasons for treating each type differently. While there are a variety of types of life insurance, there does not appear to be a reason to treat types of life insurance differently from a statutory or regulatory perspective.

In looking at other state laws and the literature, there appear to be two types of legal protection for genetic information – privacy (genetic information personal, private information) or property (genetic information the property of an individual). Privacy and non-discrimination appear to go hand in hand. If a state defines genetic information as a person's property, this has implications for research, laboratories and clinicians. This led to a discussion about the treatment of residual samples, ownership of genetic information and its implications for the commercialization of research and a recent court decision involving researchers in California. Staff will ask if there are workgroup members interested in forming a subgroup to explore the implications of defining genetic information as a person's property. For purposes of insurance, it does not appear necessary to legally protect genetic information as property.

Categorizing trends across the country regarding state laws pertaining to genetic information and insurance is very difficult. Many states passed laws to protect individuals from discrimination in the purchase or rating of various types of insurance based on genetic traits that are of no harm to the individual carrying the trait– e.g., sickle cell anemia. The Workgroup noted the information in the staff's presentation (Slide entitled "State laws") is not accurate. ACLI will provide an update to the staff to confirm

two states restrict the use of genetic information for life insurance, 8 for disability insurance and eleven for long-term care insurance.

The Workgroup then reviewed the current statutory prohibitions pertaining to the use of genetic information for health benefits, life insurance and long-term care insurance contrasting this with GINA. The staff asked if Maryland's statute for health benefits should be modified, as other states have done, to track the definitions in GINA. The staff noted that irrespective of the definitions, both Maryland's statute and GINA prohibit an insurer, nonprofit health service plan or HMO from using genetic information, genetic tests or genetic services to underwrite a health benefits' policy, rate a health benefits' policy or limit coverage under a health benefits' policy. Paul Ballard agreed to look more closely at the definitions.

The question was raised about industry standards for identifying a risk. Staff confirmed that §27-501 of the Insurance Article prohibits an insurer from refusing to underwrite or renew a risk for an arbitrary, capricious or unfairly discriminatory manner. Companies must follow actuarial standards but are each free to establish own criteria. Some wondered if this was sufficient protection for the use of genetic information for underwriting disability and life insurance. Staff noted a specific statutory provision makes it easier, from a regulatory perspective, to enforce and also affords more consistency across companies.

The meeting scheduled was then reviewed. The industry will make a presentation next time and will allow time for discussion. Staff confirmed the Workgroup may continue past two hours if needed.

## Workgroup on Genetic Testing

September 9, 2009  
Meeting Minutes

### Participants:

Paul Ballard	Jennifer Kulynych, J.D.,	Lisbeth Pettingille
Miriam G. Blitzer, Ph.D.	Ph.D.	Debbie Rivkin
John Dodge, M.D.	Honorable Roger Manno	Kimberly Robinson
Deborah Hellman	Bruce Margolis, DO	Joan A. Scott, MS, CGC
Michael Hickey	Donna Meyer	Timothy Smith
May Jung, M.D.	Matt Palmer	
Mary Kivlighan, J.D.	Susan Panny, M.D.	

### Minutes:

The Workgroup on Genetic Testing held its third meeting to review and discuss the underwriting and pricing practices of life insurers and disability insurers.

The meeting began with a recount of the conclusion of the property rights subgroup. The staff reported the subgroup reviewed HB 12 from the 2009 Legislative Session and discussed its two components, informed consent and property rights. While the information from ACLI shows 12 states have enacted statutes regarding informed consent, only two (Alaska and Florida) have enacted statutes making genetic information an individual's property. The subgroup noted informed consent has relevance to underwriting of life insurance and disability insurance but that property rights do not. Whether genetic information is an individuals' property raises a number of public policy concerns (e.g., delivery of medical care, research) and is beyond the scope of the expertise of the Maryland Insurance Administration (MIA) or the Workgroup.

The representatives of AHIP, ACLI and the League of Life and Health Insurers then provided an overview of underwriting and rating of life insurance and disability insurance policies. The background material and the presentation are posted on the MIA's website.

The Workgroup discussed the similarities and differences between life insurance, disability insurance, long-term care insurance and health insurance. The presenters noted health insurance reimburses costs to third-parties who rendered a service to the policyholder (e.g., accept assignment of benefits from the policyholder to the provider); it is thought of as a right. Life, disability and long-term care insurance directly reimburse the policyholder (e.g., no assignment of benefits) and must be "sold" by the insurer (e.g., not actively sought by the consumer). The Workgroup debated these two points. Some questioned whether the distinction between health, life, and disability insurance is as great as the industry presents. All these lines provide financial protection; currently all these lines are voluntary. There was agreement more Americans are interested in purchasing health insurance than life insurance, disability insurance, or long-term care insurance.

The presenters noted an important difference for life insurance. Life insurance policies are priced at the time the policy is issued. The price remains the same over the course of the policy. Thus, accurately predicting the risk at the time the policy is issued is very important.

Life insurers each develop their own rating tables. Rating tables are established for standard and substandard risks. The presentation provides additional technical information about how insurers calculate the mortality ratio and calculate premium based on the mortality ratio.

The presenters provided detail about the medical underwriting process. Part of this process includes ascertaining the predictive value of a particular medical test. Today, insurers do not require genetic tests; they may review a genetic test result if it is a part of the applicant's medical history. Whether the results of the genetic test would be used in underwriting depends upon the predictive value of the genetic test. With the exception of Huntington's disease, most DNA testing today does not give enough accurate information to routinely include in underwriting and rating.

The Workgroup discussed whether the potential use of a genetic test result for life insurance and disability insurance underwriting might discourage individuals from having a genetic test. The Workgroup seemed to agree genetic tests may be desirable from a public health perspective. If an individual knows he or she is at risk for a certain disease, he or she may take certain steps to mitigate this outcome. The Workgroup considered how to protect insurers from adverse selection and not negatively impact public health. Possible solutions will be reviewed and discussed at the October 5<sup>th</sup> meeting.

## Workgroup on Genetic Testing

September 17, 2009  
Meeting Minutes

### Participants:

Paul Ballard	May Jung, M.D.	Susan Panny, M.D.
Miriam G. Blitzer, Ph.D.	Lars Kristiansen	Lisbeth Pettingille
John Dodge, M.D.	Bruce Margolis, DO	Kimberly Robinson
Pat Fallon (for Delegate Manno)	Donna Meyer	Joan A. Scott, MS, CGC.
	Matt Palmer	Robert Neill, Jr

### Minutes:

The Workgroup on Genetic Testing ("Workgroup") held its fourth meeting to review and discuss personalized medicine. The meeting began with a presentation from Stephen Liggett, M.D., Professor of Medicine and Physiology and the Director of the Cardiopulmonary Genomics Program at the University of Maryland's Medical School. Dr. Liggett provided the Workgroup with a written overview, attached to the minutes.

Personalized medicine is a term used to describe medicine based on an individual's genomic information. Dr. Liggett pointed out that medicine has always been personalized, based on an individual's medical history, family history, physical examination and laboratory tests.

Dr. Liggett noted that DNA testing is different from other medical tests because once collected and stored information can be gathered from the sample for decades. It also offers the opportunity of providing quicker results than other tests currently available. However, at this point in time, genetic tests are not used routinely. For example, while we routinely refer to genetic screening for newborns, today most of this screening is biochemical and is not a genetic test per se.

Bringing the promise of personalized medicine to the community will take a longer time and requires researchers to follow individuals over a long period of time. The Workgroup discussed some of the different ways in which states have allowed hospitals to collect DNA to improve our understanding of genetic information.

Dr. Liggett divided personalized medicine into three groupings. The first is mutations that are tightly linked to specific diseases. In this grouping, we have examples of genetic tests that are routinely used today. These include sickle cell anemia, cystic fibrosis, hemophilia, fragile X syndrome and inborn errors of metabolism. These types of genetic tests are used to confirm a diagnosis.

The second is genetic variations that are associated with an increase in the risk for developing a disease. Today, genetic tests for this purpose do not have a robust odds ratio.

The third is for pharmacogenomics, predicting the response to a drug to tailor therapy. While a promising area, the tests today can assign a probability but do not yet provide a high degree of predictive value.

Dr. Liggett noted that GINA is expected to reassure volunteers participating in genomic-based studies needed to advance personalized medicine. In his experience, though, very few patients have opted not to have their DNA collected as part of research studies. Some patients do ask about the impact of participating on life and disability insurance. It was further noted that information collected for genetic research does not end up in an individual's medical file. The Workgroup seemed to agree that unless the result of the genetic test was in the medical record and the genetic test was considered predictive, it would not be used by insurers today.

STEPHEN B. LIGGETT, M.D.  
Professor of Medicine and Physiology  
Director, Cardiopulmonary Translational Program



UNIVERSITY OF MARYLAND  
SCHOOL OF MEDICINE

September 16, 2009

Ms. Beth Sammis  
Workgroup on Genetic Testing  
Maryland Insurance Administration  
300 St. Paul Place, Suite 2700  
Baltimore, MD 21202

Dear Sirs/Madam,

I have been asked to provide information on Personalized Medicine to assist in the review of Maryland's laws regarding the use of genetic information in the underwriting and rating process for life and disability insurance. Please find enclosed a brief summary of Personalized Medicine, with specific points relative to the aforementioned review.

Sincerely,

Stephen B. Liggett, M.D.  
Professor of Medicine



## Personalized Medicine

Generally, Personalized Medicine is a term that is used to describe medicine that is based on an individual's genomic information. This information could be genetic variation in a person's DNA, expression patterns of RNA or protein, or expression of biomarkers. Typically, this information has been thought to be useful for three possible uses: 1) to predict the risk of developing a disease, 2) to predict the prognosis of a disease, or 3) to predict the response to therapy (a field called pharmacogenetics or pharmacogenomics).

In reality *good* medical practice has always been "personalized." That is, the assessment of a patient is based on components of the medical history, family history, physical examination, and laboratory tests. The risk for a disease, or how a disease will progress, or the treatment plan, is in fact, individualized based on the aforementioned results. For reasons that are not entirely clear, the advent of the "genomic era" (~2001 when the sequence of the human genome was published) brought about concerns of privacy that had not been voiced before. Prior to this time, testing for genetic-based illnesses was indeed a part of routine medical care, such as for sickle cell anemia and cystic fibrosis, both being due to mutations that are quite common in the U.S. As an extension, tests for HIV and serious chronic infectious diseases such as tuberculosis and hepatitis were being performed. And, of course, biopsies and other tests were routine for the diagnosis of cancer as well. All of these results represented very personal information that would have a significant impact on health, life expectancy, etc. In essence, then, such critical information has been in the "medical record" since modern medicine began.

The concern over testing of DNA is partially based on the fact that once collected and properly stored, information can be gathered from it for decades. And, as new associations between a genetic variant and disease risk or prognosis is reported, that the test for the variant might be performed on a person's DNA that was originally collected for a specific clinical purpose, or, for research. This is not an entirely new concept, either, as many types of stored specimens (tissue, blood, plasma) can be retested with new assays.

Nevertheless, the notion that DNA represents the "totality" of a person is now ingrained, and the idea that genetic tests can tell you something about a person that will happen in the future is also accepted by the public.

However, the current status of genetic testing (or other "omics" tests as described above) is not as advanced as most people outside of the genomics field believe. The validity, predictive power, and other issues of genetic testing that come under the purview of Personalized Medicine can be described in three groupings:

1. Mutations that are tightly linked to specific diseases. Examples of these tests include those for sickle-cell anemia, cystic fibrosis, hemophilia, fragile X syndrome, and inborn errors of metabolism (many of which are used for testing newborns). These tests are highly specific and are used routinely.

2. Genetic variations that are associated with an increase in the risk for developing a disease. The influence of the variation on developing the disease is almost always not "absolute" but represents a probability, which is often influenced by ethnicity, the presence of other genetic variations, and the environment (including diet and socioeconomic issues). Particularly for so called complex diseases, such as diabetes, the odds ratios (or relative risks) for these associations are typically between 1.0 and 2.0. For example, a variant in the gene *FHIT* is associated with type 2 diabetes in the Amish with an odds ratio of 1.42, meaning that those with the variant were 1.42 times more likely to have type 2 diabetes. This is not considered a very robust ratio, but is usually what is found in complex diseases. Furthermore, the *FHIT* variant was also associated with the disease in Mexican-Americans (odds ratio 1.46) but not in Scandinavians or in Caucasians who participated in the Framingham Heart Study. These studies are quite valuable in identifying previously unknown pathways that may be involved in a disease, but the predictive value (and the error associated with that value) of a single variant is usually insufficient to make decisions regarding prophylactic measures or life expectancy. Nevertheless, as the tools and study designs become more advanced, the promise of genomic-based medicine is to have a "scorecard" of variants that together provide a strong prediction as to risk of disease. In most cases, we are not there yet.

3. Pharmacogenomics (predicting the response to a drug, so as to tailor therapy). Similar to what has occurred in category 2), a number of associations have been made between a genetic variant and the response to a given drug. This has been so for a large number of diseases, including asthma, heart failure, hypertension and diabetes. Again, though, the predictive values (and the false-positive and false-negative rates) are such that at best one can assign a probability that an individual will respond (or not), but single variants rarely provide a yes/no answer. Analogous to the disease risk example, as more variants are discovered, some type of multi-variant, composite, score may become available for drug response with a high degree of predictive value.

The Genetic Information Nondiscrimination Act (GINA). Title I of GINA prohibits genetic discrimination in health insurance and Title II of GINA prohibits genetic discrimination in employment. The Title I language prohibits insurance companies to use or require genetic information to make decisions about a person's eligibility or type of coverage. In my own experience, very few patients have opted not to have their DNA collected as part of research studies. Nevertheless, as the potential for misuse of genetic testing information becomes more recognized (as has the possibility of "identity theft"), the provisions of GINA are expected to be reassuring to volunteers who are considering participation in genomic-based studies, and the level of participation is not predicted to change in the foreseeable future.

Summary: Personalized Medicine has made some significant advances over the last decade. The use of genomic-based testing has led to the notion of one day providing a person with a high level of predictiveness as to risk for developing a disease, prognosis, and individualizing drug therapy. Currently, the predictive value for most genomic-based studies is not particularly noteworthy, except for selected monogenic disorders. As

studies have progressed, the issue of privacy of the data has emerged, including the privacy of other more traditional information that is readily extracted from the medical records. Similarly, issues regarding the misuse of genomic or other data have arisen, and GINA represents a major step in regulating how genomic information is utilized in insurance and employment.

## Workgroup on Genetic Testing

October 5, 2009  
Meeting Minutes

### Participants:

Paul Ballard	Mary Kivlighan, J.D.	Susan Panny, M.D.
Miriam G. Blitzer, Ph.D.	Jennifer Kulynych, J.D., Ph.D.	Lisbeth Pettingille
John Dodge, M.D.	Honorable Roger Manno	Debbie Rivkin
Deborah Hellman	Bruce Margolis, DO	Kimberly Robinson
Michael Hickey	Matt Palmer	Timothy Smith
May Jung, M.D.		Robert Neill, Jr.

### Minutes:

The Workgroup on Genetic Testing ("Workgroup") held its final meeting to review and discuss: (1) principles to guide public policy in the use of genetic information and genetic testing in life insurance, disability insurance and long-term care insurance; and (2) possible public policy recommendations. The Workgroup used the document distributed in advance of the meeting (attached) to guide its deliberations.

The Workgroup appeared to agree on the following principles:

- Minimize barriers to participate in genomic research
- Allow individuals to make their own decisions regarding whether to undergo genetic testing without basing this decision on the availability of insurance
- Promote fair underwriting and pricing decisions, balancing the consumer and industry view of fairness
- Minimize/deter adverse selection
- Minimize "genetic exceptionalism"
- Anticipate scientific advancement
- Minimize regulatory complexity

In considering possible public policy recommendations, the Workgroup discussed three in great detail:

1. Prohibit the use of genetic tests for life, disability and long-term care insurance under a certain dollar threshold. ("Option 1")
2. Prohibit insurers from requiring a genetic test but allow insurers to consider a genetic test an individual had as long as the genetic test had been proven to accurately confirm a diagnosis or predict a future outcome. ("Option 2")
3. No change in current law. ("Option 3")

Option 1 includes Option 2 above a certain specified threshold. A number of individuals participating in the Workgroup emphasized that genetic tests are different and while we may minimize genetic exceptionalism we cannot ignore it. In developing the options

listed above, the MIA assumed the definition of "genetic information" and "genetic test" are different. Genetic information was described as any genetic material, including family history and diagnostic tests. Genetic testing was defined as testing done with regards to DNA that had a predictive outcome. The options discussed by the group specifically addressed genetic testing, and not genetic information. The Workgroup agreed public education about genetic testing and insurance could help alleviate some of these fears.

There are social and psychological implications for an individual undergoing a genetic test and the individual needs to be prepared for these prior to taking a genetic test. The results of a genetic test have implications for the individual and for family members. There is a public fear of discrimination because we do not know the implications of our genetic make-up for all conditions.

The Workgroup discussed the feasibility of setting a threshold for life, disability and long-term care insurance. Setting a threshold assures consumers they will always have access to the financial protection afforded by life, disability and long-term care insurance. But it does increase the insurers' risk of adverse selection, which we predict would result in higher premiums for the base policy. The Workgroup considered mechanisms for reducing the risk of adverse selection such as a reinsurance mechanism.

Option 1 assumes an individual would only be able to purchase the base policy from one insurer. The Workgroup discussed whether this limitation could be imposed. Today, consumers may purchase insurance from multiple insurers for the same type of coverage. A system to share information about applicants and policyholders would have to be developed to allow the industry to decline coverage to someone who had already purchased the base policy from a competitor.

The MIA staff believes Option 1 – based on the European experience – strikes an appropriate balance between consumers and insurers as well as the principles previously identified. But the MIA staff does not believe the infrastructure is in place to carry out this option in a small state. This would be a fruitful Option for an organization like the NAIC to consider.

Option 3 is favored by the insurance industry. They note there may be scientific advances in the area of genetics and they should not be precluded from using advances that more accurately predict risks, particularly if individual applicants have this information available to them and the insurer does not thus resulting in greater adverse selection. For others, this option does little to address consumer concerns about genetic tests and insurance, a concern that may make it more difficult to achieve the advances promised by a greater understanding of genetics and medicine.

With regard to Option 2, promoted by the MIA staff, some agreed this offered some additional consumer protections for disability and life insurance similar to what exists today for long-term care insurance. The Workgroup discussed whether a sunset on any new law would give the General Assembly an opportunity to review any scientific

advances offering evidence insurers should be able to request an applicant undergo a genetic test.

Insurers maintain current law pertaining to underwriting should be sufficient to reassure consumers genetic test results are used in a fair manner. Others questioned whether underwriting is sufficiently transparent to give the public confidence this is a fair process

Additional concerns included the fact that the genes of one person provide information about that individual's relatives. The genetic testing of one individual could impact the rating of an entire family. There were also concerns about a bias created by genetic discovery. Currently, there are diseases whose genes are known and the testing provides a highly predictive outcome. There are other diseases whose genes are unknown, and there is very little accurate predictive testing available. Consumer rating would be skewed on the basis that those who are unlucky enough to have a known disease would be rated higher according to genetic testing. Those individuals who carry the gene for a relatively unknown disease would face a better rating scheme.

The Workgroup concluded without a consensus on public policy recommendations.

**Appendix 4: Genetic Tests in Disability, Long-Term Care  
and Life Insurance**

*Genetic Information and Genetic Testing:  
Insurance and Personalized Medicine*

During the 2009 Maryland Legislative Session, the Maryland General Assembly considered five bills pertaining to genetic information and genetic testing in insurance and personalized medicine. Each is summarized below:

- House Bill 1/Senate Bill 2, "Disability Insurance – Discrimination Based on Genetic Information or Tests – Prohibited" would have prohibited an insurer from using genetic information to reject, deny, refuse to renew, or increase rates on a disability contract.
- House Bill 2/Senate Bill 1, "Life Insurance and Annuities – Genetic Tests, Information, and Services – Prohibited Acts," would have prohibited an insurer from requesting, requiring, or using the results of a genetic test when issuing an annuity risk insurance policy unless the insurer demonstrated it is actuarially justified.
- House Bill 11/Senate Bill 57, "Insurance – Violation of Genetic Nondiscrimination Laws – Private Cause of Action," would have provided individuals who are injured due to an insurer's violation of genetic discrimination laws with a private cause of action.
- House Bill 12/Senate Bill 54, "Genetic Privacy – Individual's Genetic Information – Personal Property Rights," would have required an individual's informed consent prior to administering a genetic test and made an individual's genetic information the exclusive property of the individual from whom the sample was collected.
- House Bill 445 (HB 445), "Maryland Health Care Commission – Personalized Medicine – Study," would have required the Maryland Health Care Commission (MHCC) to create a formal workgroup to study issues related to the implementation of personalized medicine, including analysis the impact of GINA on Maryland's regulation of personalized medicine.

Although none of these bills passed, the Health and Government Operations Committee in the House of Delegates and the Finance Committee in the Maryland Senate asked the Maryland Insurance Administration ("MIA") to convene a Workgroup on Genetic Testing ("Workgroup") to explore the topics below to further the committees' deliberations on genetic information and genetic testing, insurance and personalized medicine:

- Current state of genetic testing;
- Availability of genetic tests;
- Means of obtaining a genetic test;
- Prevalence of genetic testing;
- Anticipated outcome of genetic testing;
- Role of genetic testing in long-term care insurance, disability insurance, and risk insurance;
- Privacy considerations related to genetic testing;
- Principles for public policy and the use of genetic testing; and
- Regulation of personalized medicine.

As requested by the committees, the MIA invited the insurance industry, the Office of the Attorney General, the Department of Health and Mental Hygiene, Johns Hopkins University, and

the University of Maryland to designate an individual to participate in the Workgroup. The sponsors of the 2009 legislation, Delegate Manno and Senator Forehand, were also invited to join the Workgroup. In addition, any other individual expressing interest in the Workgroup was allowed to participate.

The Workgroup held five meetings between June and October of 2009. Although the Workgroup agreed on some general principles to guide public policy discussions on the permitted use of genetic information and genetic testing in insurance underwriting and rating, no consensus was reached regarding the permitted use of genetic information and genetic testing in insurance.

The remainder of this report summarizes the information reviewed by the Workgroup, some of the views offered by Workgroup participants and the MIA's conclusions based on these deliberations.

### *Genetic information and genetic testing*

Genetic information is the heritable biological information coded in the nucleotide sequences of DNA or RNA. Family history and genetic tests are both sources of genetic information. Genetic tests include biochemical tests and DNA-based tests. Genetic tests:

- Confirm or rule out a known or suspected medical condition
- Predict development of a medical condition
- Determine if an individual is a carrier of a medical condition
- Determine if an embryo or fetus has a medical condition
- Determine if a newborn has a medical condition
- May be used in medical research

Today, over 1,000 genetic tests are available. While other states permit direct to consumer genetic testing, genetic tests in Maryland must be ordered by a physician and, except for research purposes, must be performed by a licensed laboratory. This helps to ensure the test's accuracy as well as patient understanding of the results. Nevertheless, the insurance industry representatives in the Workgroup expressed great concern about the consequences of direct to consumer genetic testing, a method providing the consumer with information that may not be available to the insurer during underwriting.

DNA-based genetic tests offer the promise of providing more genetic information and furthering our understanding of the relationship between genetics, the environment and health. Such information may be used to improve medical practice, to help prevent a disease or condition as well as to help tailor treatment for an individual thereby improving health outcomes. However, at this point in time, this promise has yet to be realized.

Genetic research continues to identify mutations that are tightly linked to specific diseases, genetic variations that are associated with an increase in the risk for developing a disease and predicting responses to drugs. Because such research has the potential to significantly improve medical practice, it is important to address the public's fears about genetic

tests and research. An educational campaign to improve the public's understanding of genetic information and genetic tests is one way to ameliorate these fears and help gain further support for this important research.

#### *Health and life insurance*

Health insurance is defined under Maryland law as insurance against bodily injury, disablement, and expenses incurred in prevention of sickness or dental care. Health insurance includes major medical insurance (health benefits), vision, dental, disability, long-term care, fixed indemnity, specified disease and Medicare supplemental insurance.

In Maryland, health insurance may be sold by licensed health insurers, property casualty insurers, or life insurers. Most health insurance is sold by health insurers (\$6.7 billion in premium in 2008 in Maryland) or life insurers (\$2.4 billion in premium in 2008 in Maryland). Health benefits account for about 70 percent of all health insurance written premium.

Life insurance is defined under Maryland law as insurance for which the probabilities of the duration of human life or the rate of mortality are an element of the insurance. Life insurance includes term life, whole life, variable life, universal life and universal variable life.

In Maryland, life insurance may only be sold by licensed life insurers. In 2008, there were 394 licensed life insurers who wrote \$2.6 billion in premium in Maryland.

The Workgroup focused on disability, long-term care and life insurance. In part, this was because federal and state law prohibits the use of genetic information in underwriting health benefits.

The insurance industry maintains there are important differences between disability, long-term care and life insurance on the one hand and health benefits on the other. According to the insurance industry, health benefits provide the financial ability to access health care by reimbursing health care providers, hospitals, pharmacies, and others the cost of an individual's health care whereas the benefits paid by disability, life and long term care insurance provide financial protection so that people facing serious illnesses or accidents can meet day-to-day financial obligations.

While all types of health and life insurance may be purchased on a group or an individual basis, most Americans receive health benefits through their employer and have come to expect health benefits to be a part of their compensation. Disability, long-term care and life insurance are more discretionary purchases.

If an individual's demand for insurance is positively correlated with the individual's risk of loss and the insurer is unable to allow for this correlation in the price of insurance, adverse selection occurs. Adverse selection may occur because the individual has more information about his or her health than the insurer. This difference in information is referred to as information asymmetry.

Information asymmetry is of particular concern to insurers in the individual market where the individual determines when to purchase insurance and at what amount. If the insurer is not able to accurately assess the individual's risk and charge a premium commensurate with this risk, the financial consequences to the insurer may be devastating. The financial consequences are heightened in insurance lines such as disability, long-term care and life insurance where the policy is guaranteed renewable and future premium increases may not be based on a change in the individual's health condition or claims experience.

Underwriting is the tool insurers use to minimize information asymmetry and its outcome, adverse selection. Underwriting may include a number of areas (e.g., financial), but for the purposes of exploring the use of genetic information in life and health insurance only medical underwriting is relevant.

Medical underwriting in life insurance involves an analysis of the individual applicant's mortality risk. Medical underwriting in disability and long-term care insurance involves an analysis of the individual applicant's mortality and morbidity risk. An assessment is made for the individual applicant's known and unknown diseases or conditions. Highly trained professionals with backgrounds in statistics, medicine and science develop the medical underwriting tools used in disability, long-term care and life insurance.

Currently, medical underwriting for disability, long-term care and life insurance relies on certain genetic information such as family history. But DNA-based genetic tests are not used in medical underwriting.

#### *Personalized medicine*

Personalized medicine is a term that is used to describe medical practice based on an individual's genomic information. The term is a misnomer, however, since medical practice has always been personalized. Physicians assess patients based on medical history, family history, physical examination, and laboratory tests. Based on this information, the physician determines the risk for a disease, how a disease will progress and the treatment plan.

Genomic information may improve medical practice, making it more personalized in three ways:

- Identifying mutations tightly linked to specific diseases;
- Identifying genetic variations associated with an increase in the risk for developing a disease; and
- Predicting an individual's response to a drug to tailor therapy.

Today, there are DNA-based genetic tests and non-DNA based genetic tests that allow physicians to identify mutations tightly linked to specific diseases. In these cases, it is known the individual will develop the specific disease. Examples include sickle-cell anemia, cystic fibrosis, hemophilia, and Huntington's disease.

While there are DNA-based genetic tests that have identified genetic variations associated with an increase in the risk for developing a disease, the link between the genetic variation and the environment has not been well established. Thus, the results of such tests are insufficient to make decisions regarding prophylactic measures or life expectancy.

Similarly, the link between a genetic variant and a response to a given drug has been shown for certain diseases, such as asthma, heart failure, hypertension and diabetes. However, a high degree of predictive value has yet to be achieved.

Apart from selected monogenic disorder, the predictive value of most genomic-based studies is not particularly noteworthy. Achieving the promise of personalized medicine requires more genetic research. Maintaining a legal and regulatory environment supportive of genetic research is important in attracting physicians and scientists to Maryland interested in this field. Assisting genetic research may be enhanced by permitting hospitals to collect genetic samples from all admitted patients as has been done by other states.

#### *Genetic exceptionalism*

If genetic information is qualitatively different from other forms of personal or medical information, then it stands to reason that it requires greater protection. This is known as genetic exceptionalism. Proponents of genetic exceptionalism point to three reasons why genetic information is different: it can predict disease occurrence in an individual and the individual's family members; it uniquely identifies a person; and it may be used to discriminate and stigmatize individuals.

The use of DNA-based genetic testing has heightened concerns about the use of genetic information. A 2006 survey found over 50 percent of respondents were concerned life and health insurance companies would gain unauthorized access to personal genetic information.<sup>1</sup> Proponents of genetic exceptionalism point to such concerns as reason to enact state and federal law to give greater protections to genetic information.

As the previous section suggests, whether genetic information obtained from DNA-based genetic testing can predict disease occurrence in an individual may be more complicated than proponents of genetic exceptionalism maintain. Nonetheless, public concerns and fears about genetic information and genetic testing have led the states, the federal government and other nations to limit the use of genetic information and genetic tests in certain types of insurance.

#### *Genetic information, genetic testing and insurance: statutory limitations*

Many states have prohibited the use of genetic information and genetic testing in underwriting for health benefits, a prohibition recently extended to all health benefits with the passage of the federal Genetic Information and Nondiscrimination Act ("GINA"). Unlike health benefits, the debate about the use of genetic information and genetic tests in disability, long-term care and life insurance has focused primarily on genetic tests. This is because it is very difficult to define genetic information separately from health information. Genetic information includes

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<sup>1</sup> See Alissa Johnson "Plunging into the Gene Pool" *NCSL* March 2007.

family history, a history routinely explored and permitted for a very long time during medical underwriting for disability, long-term care and life insurance.

Only a few states have limited the use of genetic testing in underwriting for disability, long-term care and life insurance. (See Appendix XXX for a complete review of state laws.) In Maryland, for long-term care insurance, insurers may not require a genetic test to obtain a policy or to charge a different rate; however, insurers may use the results of a genetic test to deny a policy or charge a different rate if the use of the genetic test is based on sound actuarial principles. See *Ins.* §18-120

Some states have gone further than Maryland in defining the responsibility of the insurer if a genetic test is to be used during medical underwriting by requiring:

- The insurer to pay the cost of the genetic test
- Notification to the applicant that a genetic test may be used
- Informed consent before the insurer may proceed with a genetic test

Only two states (Alaska and Florida) have enacted statutes making genetic information a person's property. This definition has far-reaching implications for research, laboratories and clinicians and both the MIA and the Workgroup concluded it was beyond the scope of their expertise. As current state law and GINA demonstrate, it is not necessary to define genetic information as property in order to define the permissible use of genetic information and genetic tests in medical underwriting.

Some European nations have taken other steps to limit the use of genetic tests in medical underwriting. In the Netherlands, for example, life insurers may not use previous genetic tests during medical underwriting for policies below a certain pre-determined amount. In some countries, the life insurance industry has entered into a formal moratorium to prohibit insurers from requiring an applicant undergo genetic testing.

#### *Public policy principles and public policy options*

The Workgroup agreed the following principles should be used to assess public policy options pertaining to the use of genetic testing in underwriting for disability, long-term care and life insurance:

- Minimize barriers to participate in genomic research
- Allow individuals to make their own decisions regarding whether to undergo genetic testing
- Promote fair underwriting and pricing decisions, balancing consumer and industry views of fairness
- Minimize/deter adverse selection
- Minimize genetic exceptionalism
- Anticipate scientific advancement
- Minimize regulatory complexity

The Workgroup discussed three public policy options in great detail:

- Prohibit the use of genetic tests for disability, long-term care and life insurance under a certain dollar threshold ("Option 1")
- Prohibit insurers from requiring a genetic test but allow insurers to consider a genetic test an individual has had as long as the genetic test has proven to accurately confirm a diagnosis or predict a future outcome ("Option 2")
- No change in current law ("Option 3")

A number of individuals participating in the Workgroup emphasized that genetic tests are different and while we may minimize genetic exceptionalism we cannot ignore it. There are social and psychological implications for an individual undergoing a genetic test and the individual needs to be prepared for these prior to taking a genetic test. The results of a genetic test have implications for the individual and for family members. There is a public fear of discrimination because we do not know the implications of our genetic make-up for all conditions.

Concerns were also expressed about a bias created by genetic discovery. Currently, there are diseases whose genes are known and the testing provides a highly predictive outcome. There are other diseases whose genes are unknown, and there is very little accurate predictive testing available. Consumer rating would be skewed on the basis that those who are unlucky enough to have a known disease would be rated higher according to genetic testing. Those individuals who carry the gene for a relatively unknown disease would face a better rating scheme.

Option 1 – based on the European experience – strikes an appropriate balance between consumers and insurers. It gives all consumers access to some defined minimum insurance level, irrespective of their health or genetic make-up. But it does increase the risk of adverse selection, requiring mechanisms to spread the risk among insurers to ensure none has experienced greater adverse selection than others. It also requires a common definition of a minimum threshold. Most importantly, it requires an infrastructure to ensure consumers do not take advantage of this prohibition by simply buying several basic policies from multiple insurers.

Option 3 is favored by the insurance industry. They note there may be scientific advances in the area of genetics and they should not be precluded from using advances that more accurately predict risks, particularly if individual applicants have this information available to them and the insurer does not thus resulting in greater adverse selection. For others, this option does little to address consumer concerns about genetic tests and insurance, a concern that may make it more difficult to achieve the advances promised by a greater understanding of genetics and medicine.

Option 2 offers additional consumer protections for disability and life insurance. It is similar to current Maryland law for long-term care insurance. It allows individuals to make the decision about whether to undergo genetic testing and it allows insurers to use the results of genetic tests only if the genetic test has proven valid and predictive.

Although the Workgroup did not reach a consensus on any of these options, the MIA recommends the committees consider Option 2 and has provided suggested draft language should the committees wish to consider this option during the 2010 Legislative Session. (See Appendix 4) This draft language makes the standards for the use of genetic tests uniform for disability, long-term care and life insurance but recognizes that this standard should not be the same as the national standard for health benefits because of the more voluntary, discretionary characteristics of the purchase of disability, long-term care and life insurance.

**Appendix 5: MIA Suggested Draft Language for Amendment to Offer Additional Consumer Protections (“Option 2”)**

*Amend §27-909 and delete §18-120.*

§27-909.

(a) (1) In this section the following words have the meanings indicated.

(2) [ "Gene product" means the biochemical material, either RNA or protein, made by a gene. ] (I) "FAMILY MEMBER" MEANS:

1. A DEPENDENT OF THE INDIVIDUAL; OR  
2. ANY OTHER PERSON WHO IS A FIRST-DEGREE, SECOND-DEGREE, THIRD-DEGREE, OR FOURTH DEGREE RELATIVE OF THE INDIVIDUAL OR OF A DEPENDENT OF THE INDIVIDUAL.

(II) "FAMILY MEMBER" INCLUDES A RELATIVE BY:

1. MARRIAGE OR ADOPTION;  
2. LESS THAN FULL CONSANGUINITY; AND  
3. FULL CONSANGUINITY.

(3) "FIRST-DEGREE RELATIVE" MEANS PARENTS, SPOUSES, SIBLINGS, AND CHILDREN.

(4) "SECOND-DEGREE RELATIVE" MEANS GRANDPARENTS, GRANDCHILDREN, AUNTS, UNCLES, NEPHEWS AND NIECES.

(5) "THIRD-DEGREE RELATIVE" MEANS GREAT-GRANDPARENTS, GREAT-GRANDCHILDREN, GREAT AUNTS, GREAT UNCLES, AND FIRST COUSINS.

(6) "FOURTH-DEGREE RELATIVE" MEANS GREAT-GREAT GRANDPARENTS, GREAT-GREAT GRANDCHILDREN, AND CHILDREN OF FIRST COUSINS.

(7) (i) "Genetic information" means, WITH RESPECT TO ANY INDIVIDUAL, information ABOUT:

1. [ about chromosomes, genes, gene products, or inherited characteristics that may derive from an individual or a family member ] THE INDIVIDUAL'S GENETIC TESTS;

2. [ obtained for diagnostic and therapeutic purposes ] THE GENETIC TESTS OF FAMILY MEMBERS OF THE INDIVIDUAL; and

3. [obtained at a time when the individual to whom the information relates is asymptomatic for the disease] **THE MANIFESTATION OF A DISEASE OR DISORDER IN FAMILY MEMBERS OF THE INDIVIDUAL.**

(ii) "Genetic information" [does not include] **INCLUDES WITH RESPECT TO ANY INDIVIDUAL, ANY REQUEST FOR, OR RECEIPT OF GENETIC SERVICES, OR PARTICIPATION IN CLINICAL RESEARCH WHICH INCLUDES GENETIC SERVICES, BY THE INDIVIDUAL OR ANY FAMILY MEMBER OF THE INDIVIDUAL.**

[1. routine physical measurements;  
2. chemical, blood, and urine analyses that are widely accepted and in use in clinical practice;  
3. tests for use of drugs; or  
4. tests for the presence of the human immunodeficiency virus.]

(III) **"GENETIC INFORMATION" DOES NOT INCLUDE INFORMATION ABOUT THE SEX OR AGE OF ANY INDIVIDUAL.**

[ (4) ] **(8)** "Genetic services" [means health services that are provided to obtain, assess, and interpret genetic information for diagnostic and therapeutic purposes and for genetic education and counseling.] **MEANS:**

**(I) A GENETIC TEST;**  
**(II) GENETIC COUNSELING, INCLUDING OBTAINING, INTERPRETING OR ASSESSING GENETIC INFORMATION; OR**  
**(III) GENETIC EDUCATION.**

[ (5) ] **(9)** (I) "Genetic test" [means a laboratory test of human chromosomes, genes, or gene-products that is used to identify the presence or absence of inherited or congenital alterations in genetic material that are associated with disease or illness.] **MEANS AN ANALYSIS OF HUMAN DNA, RNA, CHROMOSOMES, PROTEINS, OR METABOLITES, THAT DETECTS GENOTYPES, MUTATIONS, OR CHROMOSOMAL CHANGES.**

**(II) "GENETIC TEST" DOES NOT INCLUDE:**

**1. AN ANALYSIS OF PROTEINS OR METABOLITES THAT DOES NOT DETECT GENOTYPES, MUTATIONS, OR CHROMOSOMAL CHANGES; OR**

2. AN ANALYSIS OF PROTEINS OR METABOLITES THAT IS DIRECTLY RELATED TO A MANIFESTED DISEASE, DISORDER, OR PATHOLOGICAL CONDITION THAT COULD REASONABLY BE DETECTED BY A HEALTH CARE PROFESSIONAL WITH APPROPRIATE TRAINING AND EXPERTISE IN THE FIELD OF MEDICINE INVOLVED.

(10) "HEALTH BENEFIT PLAN" HAS THE MEANING STATED IN §15-1401 OF THIS ARTICLE.

(b) [ This section does not apply to life insurance policies, annuity contracts, long-term care insurance policies, or disability insurance policies.

(c) An] WITH RESPECT TO A HEALTH BENEFIT PLAN, AN insurer, nonprofit health service plan, or health maintenance organization may not:

(1) use a genetic test, the results of a genetic test, genetic information, or a request for genetic services, to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms or conditions of, or otherwise affect a health insurance policy or contract;

(2) request or require a genetic test, the results of a genetic test, or genetic information for the purpose of determining whether or not to issue or renew THE health benefits [coverage] PLAN; or

(3) release identifiable genetic information or the results of a genetic test to any person who is not an employee of the insurer, nonprofit health service plan, or health maintenance organization or a participating health care provider who provides medical services to insureds or enrollees without the prior written authorization of the individual from whom the test results or genetic information was obtained.

[ (d) ] (C) WITH RESPECT TO DISABILITY INSURANCE, LONG-TERM CARE INSURANCE OR LIFE INSURANCE, AN INSURER:

(1) MAY USE GENETIC INFORMATION TO REJECT, DENY, LIMIT, INCREASE THE RATES OF OR OTHERWISE AFFECT A POLICY OR CONTRACT, TO THE EXTENT THE USE OF THE GENETIC INFORMATION:

- (I) IS BASED ON SOUND ACTUARIAL PRINCIPLES; AND
- (II) MEETS THE REQUIREMENTS OF §27-501 OF THIS ARTICLE;

(2) MAY NOT REQUIRE A GENETIC TEST TO REJECT, DENY, LIMIT, INCREASE THE RATES OF OR OTHERWISE AFFECT A POLICY OR CONTRACT; OR

(3) MAY NOT RELEASE IDENTIFIABLE GENETIC INFORMATION TO ANY PERSON WHO IS NOT AN EMPLOYEE OF THE INSURER WITHOUT THE

**PRIOR WRITTEN AUTHORIZATION OF THE INDIVIDUAL FROM WHOM THE GENETIC INFORMATION WAS OBTAINED.**

(d) Disclosure of identifiable genetic information to **ANY PERSON WHO IS NOT** an employee **UNDER SUBSECTION (B)(3) OR (C)(3) OF THIS SECTION** or A health care provider authorized under subsection [ (c)(3) ] **(B) (3)** of this section shall only be for the purpose of:

- (1) providing medical care to patients; or
- (2) conducting research that has been approved by an institutional review board established in accordance with federal law.

(e) The authorization described in subsection [ (c)(3) ] **(B)(3)** AND (C)(3) of this section is required for each disclosure and shall describe the individual or entities making the disclosure, to whom the disclosure is to be made, and the information to be disclosed.

**(f) IN ORDER TO DETERMINE AN INSURER'S COMPLIANCE WITH THE REQUIREMENTS UNDER SUBSECTION (C) (1) OF THIS SECTION, THE COMMISSIONER MAY ARRANGE FOR AN INDEPENDENT REVIEW ORGANIZATION TO REVIEW AN INSURER'S USE OF GENETIC INFORMATION AT THE INSURER'S EXPENSE.**

(G) (1) For purposes of this subsection, §§ 4-113, 4-114, 27-501, and 27-505 of this article apply to nonprofit health service plans and health maintenance organizations.

(2) The Commissioner may issue an order under §§ 4-113, 4-114, 27-501, and 27-505 of this article if the Commissioner finds a violation of this section.

**Appendix 6: Industry Response to Draft Report**



The League of  
Life and Health Insurers  
of Maryland



November 24, 2009

Ms. Beth Sammis  
Deputy Commissioner  
Maryland Insurance Administration  
200 St. Paul Place, Suite 2700  
Baltimore, Maryland 21202

Via Email and Regular Mail

RE: Workgroup on Genetic Testing Report

Dear Ms. Sammis:

This letter is submitted on behalf of the American Council of Life Insurers (ACLI), America's Health Insurance Plans (AHIP) and The League of Life and Health Insurers of Maryland (The League).

ACLI, AHIP and The League (collectively "we") greatly appreciate the hard work of the Maryland Insurance Administration (MIA) in organizing and convening a Workgroup on Genetic Testing (Workgroup), as requested by the Health and Government Operations Committee in the House of Delegates and the Finance Committee in the Maryland Senate.

The MIA has prepared a Workgroup Report entitled - Genetic Information and Genetic Testing: Insurance and Personalized Medicine (Report). Per page two of the Report, the Report is a summary of the information reviewed by the Workgroup, some of the views offered by the Workgroup participants and the MIA's conclusions based on these deliberations: Again, we appreciate the hard work of the MIA in putting together this Report and the opportunity to provide comments.

Delegate Peter Hammen requested in his February 11, 2009 letter to Insurance Commissioner Tyler that the MIA take the lead in convening the work group and further asked that the "work group provide the General Assembly with information about the current state of genetic testing, the availability of genetic tests, the means of obtaining a genetic test (laboratory, Dr. office, internet), prevalence of genetic testing, the anticipated future of genetic testing, the role of genetic testing in long term care, disability and life insurance, privacy considerations related to genetic testing and principles for public policy on the use of genetic testing."

In accordance with Delegate Hammen's request, we respectfully offer several amendments to the Report, which are included in the enclosed Amended Report as text in red. In addition, we respectfully suggest that the MIA's recommendations for which there was no consensus be clearly distinguished from the principles for public policy on which there was consensus.

Lastly, Appendix 4 of the Report attempts to recodify the existing law applicable to health benefit plans and long term care insurance into one statute and to incorporate provisions applicable to life insurance and disability insurance. Based on our review of the proposal we have the following comments and concerns:

Definitions:

The proposal adopts the definitions used in the Genetic Information Nondiscrimination Act of 2008 (GINA). GINA applies to health benefits and does not extend to long term care insurance, disability insurance, or life insurance. As such, the industry supports language reflecting current GINA definitions as it relates to traditional health insurance but we do not, however, believe that it is appropriate to extend GINA's definitions to lines of insurance beyond those for which it was intended. Our position has been shared with the workgroup in our letter of October 2, 2009.

Prohibition on the request of a genetic test for life and disability insurance:

The proposal prohibits an insurer from requesting that an applicant take a genetic test in connection with life or disability insurance. As was discussed in the workgroup, insurers are not currently requesting applicants to take genetic tests. However, as genetic tests become more predictive and accurate, we believe there will be an appropriate use for genetic testing in the screening of applicants for insurance. We are extremely concerned about the impact of adverse selection if insurers are prohibited in the future from requesting genetic tests when appropriate. We believe adverse selection will be more prevalent when genetic tests become more predictive, less expensive and more readily available to the public without inclusion in the medical record. We therefore do not believe that it is appropriate to introduce this prohibition into Maryland's law at this time, especially as significant advances in genetic testing are anticipated in the near future.

Inclusion of a review by an independent review organization:

The proposal includes a review by an independent review organization (IRO). This concept was only briefly discussed within the workgroup and is not reflected in the minutes as part of the substantive discussion. While the Commissioner may engage experts as he deems necessary today, the introduction of an IRO in this context is novel in Maryland and novel in the country and warrants greater discussion. We have questions and concerns about the implementation of this provision and would hope for a more thorough conversation prior to inclusion in legislation.

Thank you again for convening the workgroup, organizing all the meetings, and preparing the Report. We hope to continue to work with all participants of the work group to address any concerns that consumers or the General Assembly have regarding the use of genetic testing by the insurance industry.

Signed,

*American Council of Life Insurers*

*The League of Life and Health Insurers of Maryland*

*America's Health Insurance Plans*