SB0212_MedChi, AMA_Genetic Testing Protection Act

Uploaded by: Danna Kauffman

Position: FAV

MedChi

The Maryland State Medical Society
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Baltimore, MD 21201-5516
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AMA

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330 N. Wabash Ave., Suite 39300
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ama-assn.org

TO: The Honorable Melony Griffith, Chair
Members, Senate Finance Committee
The Honorable Katherine Klausmeier

FROM: Danna L. Kauffman
Pamela Metz Kasemeyer
J. Steven Wise
Andrew G. Vetter
Christine K. Krone
410-244-7000

James L. Madara, MD (AMA)
Wes Cleveland (AMA)

DATE: February 8, 2023

RE: **SUPPORT** – Senate Bill 212 – *Genetic Testing – Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023)*

The American Medical Association (AMA) and the Maryland State Medical Society (MedChi), the largest physician organization in Maryland, **support** Senate Bill 212. Among other provisions, Senate Bill 212 prohibits carriers that offer life insurance, long–term care insurance, and disability insurance policies or contracts from taking certain coverage actions (e.g., denying, limiting, rejecting, increasing rates, etc.) based on whether an applicant or policy or contract holder has requested or undergone genetic testing or the results of the genetic testing.

The increasingly common use of genetic information, both inside and outside of the clinical setting, combined with the negative impact of the fear of genetic discrimination on patient care, make it essential that robust and comprehensive protections against genetic discrimination be enacted. Senate Bill 212 provides such protections in non-health insurance markets and, if enacted, would be a national model for other states to follow.

Genomic-based technologies are becoming an increasingly routine part of medical care. Every newborn, for example, undergoes a panel of genetic tests at birth to detect inherited conditions that are vitally important to treat early in life. Several clinical guidelines now include genetic testing, and the safe and effective use of many drugs requires knowledge of the patient's genotype. Genetic tests are available for risk assessment, diagnosis, and/or management of thousands of diseases. Moreover, whole-genome sequencing is gaining traction as a useful clinical tool. Genomic data is also increasingly common in non-clinical applications. Direct-to-consumer genetic testing companies analyze customers' DNA to reveal information about both medical and non-medical traits, and genealogy services analyze customers' DNA samples to deliver information on genetic ethnicity. With more frequent use of technologies that involve analysis of patients' genomic information, the potential for misuse and discrimination grows.

Genetic discrimination and fears thereof negatively impact patient care. Knowing that their genetic information may have financial repercussions in insurance markets, some patients avoid seeking genetic counseling or refuse to undergo genetic testing, resulting in serious health implications for individuals for whom genetic testing could be beneficial. Given the rapid advancement of genomic testing available to inform diagnostic and therapeutic decision-making across a wide and growing spectrum of diseases, forgoing genetic testing when appropriate impedes optimal patient care. Even among those who do undergo genetic testing, many withhold test results from their physicians or request that genetic information be withheld from the medical record. This lack of information can have detrimental effects on future care of the patient as treating physicians unfamiliar with the patient will have no record of genetic test results. Moreover, fears of discrimination hinder the open and honest patient-physician communication that is essential in the patient-physician relationship.

The Genetic Information Nondiscrimination Act (GINA), passed by Congress in 2008, is intended to protect individuals from genetic discrimination by health insurers and employers. While GINA has afforded important protections, it left unaddressed a number of areas in which individuals may experience genetic discrimination, including in areas of disability, long-term care, and life insurance. Senate Bill 212 addresses the shortcomings of GINA by extending protection against genetic discrimination with respect to disability, long-term care, and life insurance.

Therefore, enactment of Senate Bill 212 will provide needed protection to patients who are vulnerable to genetic discrimination, help foster patient trust and engagement in cutting-edge genomic based care, and make Maryland a leader in protecting patients from genetic discrimination. The AMA and MedChi urge a favorable vote.

AMA contact:

On behalf of James L. Madara, MD
CEO and Executive Vice President, AMA
Wes Cleveland
Senior Attorney, AMA Advocacy Resource Center
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(312) 464-4503

SB212_GeneticTesting_KennedyKrieger_support.pdf

Uploaded by: Emily Arneson

Position: FAV

Kennedy Krieger Institute

DATE: February 8, 2023 **COMMITTEE:** Senate Finance
BILL NO: Senate Bill 212
BILL TITLE: Genetic Testing - Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023)
POSITION: Support

Kennedy Krieger Institute supports Senate Bill 212 - Genetic Testing - Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023).

Bill Summary:

Senate Bill 212 prohibits life insurance, long-term care insurance and disability insurance policies from denying or limiting coverage based on genetic test results.

Background:

Kennedy Krieger Institute is an internationally recognized institution dedicated to improving the lives of children and adults with developmental disabilities and disorders of the brain, spinal cord and musculoskeletal system. The Institute serves over 27,000 patients per year, a significant portion of whom have a genetic basis for their disability. Kennedy Krieger currently employs five certified genetic counselors who care for over 1,000 patients per year.

Genetic counselors are Master's-trained healthcare professionals who have specialized education in medical genetics and counseling to provide personalized guidance to patients regarding their genetic health. KKI's genetic counselors are vital members of the medical team, working alongside physicians, nurse practitioners, and therapists to provide comprehensive patient care. Genetic counselors play crucial roles in selection of appropriate genetic tests and interpretation of results, facilitating decision-making, as well as educating and providing emotional support to patients and their families.

Rationale:

The rapid growth of medical genetics has affected virtually all areas of medicine. Over the past decade, advances in genomic technology and research have elucidated the genetic basis of a vast array of health conditions including neurodevelopmental disorders. Research has also identified promising pathways to targeted therapeutics. Genetic counselors are vital to translating these discoveries into clinical care and attaining the goal of precision medicine.

This legislation covers an important gap in the federal Genetic Information Nondiscrimination Act (GINA). GINA only prohibits health insurance and employers from using genetic information in coverage/employment decisions. Patients and families are often hesitant to proceed with genetic testing for fear that they wouldn't be able to get life, long-term care, or disability insurance in the future. At Kennedy Krieger, we have had families decline exome sequencing for their child out of this concern, which negatively impacts the child's care.

Kennedy Krieger Institute requests a favorable report on Senate Bill 212.

Emily Arneson – AVP Government Affairs – arneson@kennedykrieger.org or 443-631-2188
707 North Broadway Baltimore, Maryland 21205 (443) 923-9200/Telephone (443)923-9125/Facsimile

SB 212 ALS Testimony Rothstein.pdf

Uploaded by: Jeffrey Rothstein
Position: FAV

Jeffrey D. Rothstein, M.D. Ph.D.
John W. Griffin Director of the Pedersen Brain Science Institute
Professor of Neurology and Neuroscience

Pedersen Brain Science Institute
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JOHNS HOPKINS
SCHOOL of MEDICINE

February 7, 2023

Re: SB 212

Dear Senators,

I am here today to provide support for the genetic testing protection act of 2023 (SB212). I am a Professor of Neurology and Neuroscience at the Johns Hopkins School of Medicine. My specialty is neuromuscular disease especially amyotrophic lateral sclerosis. I've practiced at Johns Hopkins since 1986 and founded the Johns Hopkins ALS clinic in 1995. We run one of the largest ALS clinics in the United States supported by an outstanding team of health professionals dedicated to alleviating suffering from this disease and carrying out fundamentally important research. in addition, I have run dozens of experimental clinical trials in ALS in hopes of advancing new therapies. I also run a basic science lab focusing on understanding the causes of ALS and aiding in developing new experimental therapies. This research in fact led to the first FDA-approved drug for ALS in 1995, and supported multiple subsequent national and international clinical trials. I founded the Robert Packard Center of ALS research at Johns Hopkins 25 years ago to advance Preclinical Research to identify new therapies and understandings of the disease by engaging top-line researchers from around the world to work together collaboratively to tackle this disease.

In my career, to date, at Johns Hopkins I have seen or evaluated well over 10,000 ALS patients and am quite familiar with the diagnosis and course of this terrible disease. To remind you ALS is a progressive invariably fatal neuromuscular disease robbing patients of their ability to carry out any voluntary muscle activity ultimately culminating in death due to respiratory failure …that is suffocation. It is one of the most devastating adult diseases. There is no curative therapy—but genetic therapies provide incredible and realistic hope. Today we know that ALS can be inherited in a subpopulation of patients. In fact, all patients today are tested for genetic mutations that underlie ALS, as some of these mutations can be found in people without any family history of the disease. Advances in medicine especially what are known as gene therapies have had a tremendous impact in changing the course of ALS. Excitingly, in only a few weeks the newest gene therapy comes before the FDA with a high likelihood of approval. These new genetic-based therapies can offer the possibility of extending life by many years and possibly even halting the progression of the disease. In fact, trials now are administering the gene therapies even before the disease begins thereby providing the real opportunity of an individual never actually succumbing to the disease. These advances for patients are only possible because of the ability to carry out genetic testing without any repercussions from at times injurious and disruptive insurance companies, in my long experience, which can often impede the ability of patients to be afforded top-line care and thereby enhance the quality of life. The proposed bill would certainly act to substantially protect patients against this disruption of proper care and the ability to understand their own health future.

I strongly support the passage of this bill for not only my patients but for all of you who one day may face such medical trauma.

Sincerely,
Jeffrey D. Rothstein
Jeffrey D. Rothstein MD, PhD
The John W. Griffin Director of the Pedersen Brain Science Institute
Professor of Neurology and Neuroscience

The GTPA Coalition Written Testimony.pdf

Uploaded by: Jenna Massoni

Position: FAV

The GTPA Coalition

A group of organizations working together to end discrimination for individuals receiving genetic tests.

February 8, 2023

The Honorable Chair Griffith, Vice Chair Klausmeier, and Members of the Finance Committee

RE: SB 212 – The Genetic Testing Protection Act of 2023

Position: SUPPORT

We, the undersigned, represent hundreds of thousands of Marylanders who have genetic disorders. We have come together and are writing in strong support of the Genetic Testing Prohibition on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023).

The Genetic Information Nondiscrimination Act (GINA) prevents health insurers and employers from discriminating against an individual, based on their genetic information. Unfortunately, this federal legislation did not extend to 3 types of insurances: Life, Long-Term Care, or Disability Insurance.

Currently 14 states have an extension of GINA, or a GINA 2.0, adding protections for Life, Long-Term Care, or Disability Insurance. In 2020, Florida passed House Bill 1189, which prohibited life insurers and long-term care insurers from discriminating an individual based on genetic tests. In 2008, Maryland passed HB29 that prevented Long-Term Care insurers from discriminating based on genetic information. We have not seen adverse effects on premiums due to the passage of that legislation. Our goal in Maryland is to bring Life Insurance and Disability insurance up to the same standard to prohibit those insurers from canceling, limiting, increasing the premium, or denying coverage based on genetic information.

Our intention for this legislation is to avoid discrimination that our patients and advocates *have* experienced. Genetic tests are helpful information for individuals as they make life decisions for themselves and/or their families. They should not be treated differently, discriminated against, or delay receiving a genetic test because they fear insurers will deny coverage or increase or rates due to their genetics.

We thank you for your time and ask that you support this legislation with a favorable report.

Signed,

ALS ASSOCIATION

THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH

FORCE Facing Hereditary Cancer EMPOWERED

OCRA ovarian cancer research alliance

PTEN WORLD

MarylandRARE Advocacy in Action

American Kidney Fund

NPAM NURSE PRACTITIONER Association of Maryland

SUSAN G. KOMEN

PTEN Hamartoma Tumor Syndrome Foundation

LI-FRAUMENI SYNDROME LFSA ASSOCIATION

ALS Testimony 2023 Final .pdf

Uploaded by: John Knowles
Position: FAV

Madam Chair and Members of the Senate Finance Committee:

Thank you for the opportunity to speak with you today about SB 212, the Genetic Testing Protection Act. This important piece of legislation could save the lives of future generations, potentially including my relatives. My name is John Knowles, my wife Teri was diagnosed with ALS in March of 2021. Her identical twin sister Mary died from ALS is 2013 and her sister Patty died from it in 2020.

When Mary was diagnosed there was no history of ALS in our family. Diagnosis was done through a process of elimination as there are no blood tests or any tests (for that matter) that confirm the diagnosis. There are, however, genetic tests that indicate a person may have a gene that is linked to ALS, but even these tests only provide a possibility.

Teri comes from a family of 7 sisters. We live in Ashton, MD and other family members live in Germantown, Mt Airy, Frederick, Brunswick, and Frostburg, All the daughters were married and together produced 16 children and currently a next generation of 3 children. The children (including my own) are all at the time in their lives when they are marrying and adding to the family. Several of them have undergone genetic testing but most of them have not. It is sobering when the geneticist doing the testing warns you that if you carry a gene defect linked to ALS, it will likely cause you to either pay higher insurance rates or to be denied insurance altogether. So, they suggest, if you are contemplating getting life insurance, long term care insurance or disability insurance you should get it before you get tested.

Back in 2009 when Mary was diagnosed, the prognosis was bleak and there was only one drug available to help slow the progress of ALS. Today I am happy to share there are 3 approved drugs to slow the process and that there are numerous drugs under development (and) in various stages of testing that show promise on slowing and hopefully curing the disease. We are teetering on the pinnacle of so many companies and researchers finding a cure.

Some of these treatments may one day be used to treat non-symptomatic patients who have one of the genetic defects. But without genetic testing, Maryland citizens who could get early proactive treatment won't because they’ve put it off due to concerns about being able to get insurance.

Today my wife Teri is slowly getting weaker. The progression of the disease is following the same path we saw in Mary and Patty. She is on two of the drugs approved to slow the disease and is enrolled in one of the trial drugs currently being tested. Teri recognized early onset of the disease because she is a physical therapist who also helped care for her two sisters as ALS took away their strength and the ability for their muscles to work. After her second sister Patty was diagnosed, it was evident that it was the familial version and since Teri shared identical DNA with her twin, we knew she had the genetic defect even without genetic testing. It was a major factor in both of us retiring early to have as many years together as possible.

I mentioned earlier that some of our relatives have undergone genetic testing. They did this in order to be involved in a national study that is following relatives of patients with familial ALS to try and learn why some people develop it and others don't. With that said, they underwent testing knowing that it may have a negative impact on them (but hopefully will assist with finding a cure). For our family and others like us, passing of this legislation will take away one worry and it will provide an avenue for those who want to take genetic testing to discover if they have a gene defect to be open to being involved in studies and future treatments to prevent them from developing this debilitating disease.

As someone who has been impacted by insurance companies canceling insurance due to my wife's diagnosis, I can share that my life already has enough complications without an insurance company, that has profited from my premiums, deciding that her diagnosis should allow them to cancel our policy.

I'll close by simply saying…if you, your family or friends have never been impacted by a diagnosis of ALS, be thankful – watching your loved one slowly become weaker, eventually losing strength in every body muscle – is heartbreaking.

Thank you for taking the time to listen to our story and for your support for this important legislation.

Kuldip_GTPA Written Testamony_020823.pdf

Uploaded by: Kuldip Dave

Position: FAV

ALS ASSOCIATION

February 8, 2023

The Honorable Melony Griffith
Chair, Senate Finance
Room 3 East Wing, Miller Senate Office Building,
11 Bladen Street, Annapolis, MD 21401-1991

The Honorable Chair Griffith, Vice Chair Klausmeier, and Members of the Finance Committee

RE: SB 212 – The Genetic Testing Protection Act of 2023

Position: SUPPORT

My name is Kuldip Dave, Ph.D., and I am Senior Vice President for Research at The ALS Association. I am writing today in support of SB 212: The Genetic Testing Prohibition on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023), but most importantly, in support of the 224 families with ALS we currently serve in the state of Maryland as well as the tens of thousands more affected by the disease across the country.

One of the greatest scientific achievements of our time was mapping the human genome, a project that was led in Maryland. Now, the state and this Committee have the opportunity to lead the way in advancing medicine yet again through The Genetic Testing Protection Act, which if passed, will provide the protections needed to realize the full benefits of genetic science.

In 2019, researchers from Harvard University and the University of Queensland in Australia found that 40% of diseases have a genetic component. This includes ALS. ALS is a devastating disease that progressively robs people of their ability to move, speak, eat, and breathe. There is no way to stop or reverse this deterioration once it starts, meaning that most people only live for 2-5 years after being diagnosed.

Although there is still no cure, we are living in an era of unprecedented change in ALS care catalyzed by the knowledge we’ve gained about the genetic underpinnings of the disease. We estimate that roughly 10-15% of ALS is driven by gene mutations that are either passed down in families or occur randomly during development. So far, researchers have identified more than 40 genes that either cause or increase a person’s risk of developing ALS – 30 of which were discovered in the last decade alone.

It is possible that the first genetically targeted treatment for ALS will be approved this year. At least 10 other therapies targeting ALS-linked genes are being tested in clinical trials with almost a dozen more being developed preclinically. Currently, six of these 10 therapies are being tested by patients in Maryland by scientists like Drs. Jeffrey Rothstein and Nicholas Maragakis at Johns Hopkins and researchers at the NIH Clinical Center in Bethesda.

One such study currently underway at Johns Hopkins goes even further. It is trying to prevent ALS from developing – or perhaps delay the onset of the disease – in people with mutations in a gene known as *SOD1* who have no ALS symptoms. *SOD1* was the first gene discovered to be linked to ALS. Imagine if we establish this proof of concept – we could stop ALS before it starts in genetically at-risk individuals and save the economic, societal, and personal costs incurred after the diagnosis of this terrible disease.

Despite the tremendous benefits this research could provide to individuals and the entire ALS community, it is difficult and time-consuming to recruit participants because few people with ALS and their family members know their genetic status. Fear of their genetic information being used against them is one reason why people say they don't get tested.

Thus, the threat of genetic discrimination creates a serious dilemma for Marylanders – risk their physical health because they don't know their genetic status or risk their financial health because they do.

The Genetic Testing Protection Act will help allay this fear of discrimination by putting protections in place for accessing life, long-term care, and disability insurance by people who have undergone genetic testing, requested genetic testing, or received genetic test results. Such protections will not only benefit those living in the state, but through the amazing science being done in Maryland, bring life-changing new genetic therapies to everyone who needs them faster.

For all these reasons, I respectfully request your support for The Genetic Testing Protection Act. Thank you to Senator Klausmeier for introducing this legislation and to the members of the Senate Finance Committee for your time and consideration.

Sincerely,

Kuldip Dave, Ph.D.
Senior Vice President, Research
The ALS Association
Kuldip.Dave@als.org

MDSB212_ GTPA Written Testimony_ALS Assn.pdf
Uploaded by: Lindsay Gill
Position: FAV

ALS ASSOCIATION

February 8, 2023

The Honorable Melony Griffith
Chair, Senate Finance
Room 3 East Wing, Miller Senate Office Building,
11 Bladen Street, Annapolis, MD 21401-1991

RE: SB 212 – The Genetic Testing Protection Act of 2023
Position: SUPPORT

The Honorable Chair Griffith, Vice Chair Klausmeier, and Members of the Finance Committee:

On behalf of all people living with ALS, including the 224 families we currently serve in Maryland, **we respectfully request your support for Senate Bill 212: the Genetic Testing Protection Act of 2023.** If passed, life insurance, long-term care insurance, and disability insurance companies operating in the state would not be able to charge higher premiums or refuse to insure a patient that has undergone genetic testing, requested genetic testing, or because of the results of a genetic test.

Amyotrophic lateral sclerosis (ALS), also commonly known as “Lou Gehrig's disease,” is a fatal progressive neurodegenerative disease that slowly robs a person’s ability to walk, talk, eat, and eventually breathe. There is no cure, and we do not know what causes ALS.

The ALS Association is the largest philanthropic funder of ALS research in the world. The Association funds global research collaborations, assists people with ALS and their families through its nationwide network of chapters and certified clinical care centers, and advocates for better public policies for people with ALS. The ALS Association builds hope and enhances quality of life while urgently searching for new treatments and a cure.

At The ALS Association, our goal is to make ALS a livable disease by 2030. Genetic testing is a critical component to understanding the disease, treating the disease, and hopefully preventing the disease.

We do know that at least 10-15% of people with ALS have familial ALS, meaning they have a specific gene mutation that is hereditary. This specific population is unique, and we are seeing clinical trials for gene therapies to treat familial ALS across the country, including here in Maryland at Johns Hopkins. We also know that the more people participate in genetic testing, the more companies are incentivized to invest in gene therapy trials for a variety of rare diseases.

Under federal law, the Genetic Information Nondiscrimination Act (GINA), health insurers are prohibited from using information learned through genetic testing – such as a gene mutations linked to ALS – to deny coverage or engage in price discrimination. Employees are likewise protected from being fired based on genetic tests. But life insurance, long-term care insurance, and disability insurance companies are not covered under GINA.

SB 212 will allay the fear of discrimination that Marylanders may feel when trying to obtain these types of plans. This bill will put protections in place to increase access and affordability of these plans. Genetic testing and genetic counseling are crucial to people living with ALS and it helps to inform earlier diagnosis, treatment, and important life decisions.

The ALS Association thanks Senator Klausmeier for introducing this legislation. Thank you for your time and your consideration. For all these reasons, we respectfully request your support for SB 212.

Sincerely,

Lindsay Gill
Managing Director, Advocacy
The ALS Association
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Kara Nett Hinkley, MPP
Vice President, State Policy
The ALS Association
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Melanie Lendnal, Esq.
Senior Vice President, Policy & Advocacy
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FORCE_SB212 Comments_Oral.pdf

Uploaded by: Lisa Schlager

Position: FAV

FORCE
Facing Hereditary Cancer **EMPOWERED**

February 8, 2023
RE: SB 212 – The Genetic Testing Protection Act of 2023
Position: SUPPORT

Thank you for the opportunity to comment on Senate Bill 212. Please note that more extensive comments have been submitted as written testimony.

FORCE is a national nonprofit that advocates for people facing hereditary cancers. Most of our constituents carry an inherited genetic mutation that increases their cancer risk.

For instance, causing up to 60% risk of colon cancer, Lynch Syndrome affects about 1 in 300 people. While this number is sobering, the good news is that these cancers can be prevented or detected earlier when they are easier to treat.

Medical guidelines recommend these individuals undergo more intensive, more frequent cancer screenings starting at younger ages. People with Lynch mutations begin screening colonoscopy every 1-2 years between the ages of 20-25. If polyps are found, they are removed, eliminating the chance that they become cancerous.

An estimated 10% of Americans carry an inherited mutation that increases their cancer risk. With genetic testing, we can easily identify these people. **Awareness and evidence-based interventions empower members of our community to be proactive with their health, and reduce their risk, making them strong candidates for insurance.** Why are we penalizing them?

The federal GINA law falls short of providing comprehensive protections. Many members of our community have been denied or charged much higher rates for life, disability and long-term care insurance. Some people refuse genetic testing, fearing that it that will impact their ability to get insurance. This doesn't mean they don't have a genetic mutation; it means they are choosing to be uninformed due to the insurance consequences.

Maryland should prohibit insurers from considering genetic information in their coverage decisions. We urge you to endorse SB212, ensuring that all Maryland residents have access to the insurance they need.

SB212 Testimony 2-3-2023.pdf genetic testing discr

Uploaded by: Mat Rice

Position: FAV

Genetic Testing - Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023) SB212
Senator Klausmeier Committee: Finance   Hearing: February 8,2023 Position: Favorable

Prohibiting carriers that offer life insurance, long-term care insurance, and disability insurance policies or contracts from taking certain action regarding coverage based on whether an applicant or policy or contract holder has requested or undergone genetic testing or the results of the genetic testing; and requiring the Maryland Department of Health to review and update certain materials relating to genetic testing on or before April 1, 2024.

Dear members of the Finance committee,

People on the Go of Maryland, (People on the Go) the statewide self-advocacy organization, ran for and by those with intellectual and/or developmental disabilities (IDD) offers this written testimony in support of SB212 Genetic Testing - Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023) This bill would ensure that insurance companies cannot discriminate against anybody, including people with disabilities, if said people have chosen to undergo genetic testing, both in the past and present. People on the Go supports any bill that fights against discrimination. We strongly recommend a favorable report.

If there are any questions, please contact Cody Drinkwater, Public Policy Assistant

percorion@aim.com
443-866-3055

2023 ACNM SB 212 Senate Side FAV.pdf

Uploaded by: Michael Paddy

Position: FAV

AFFILIATE OF
AMERICAN COLLEGE of NURSE-MIDWIVES
With women, for a lifetime®

Support

Senate Bill 212 – Genetic Testing - Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023)

Senate Finance Committee

February 8, 2023

The Maryland Affiliate of the American College of Nurse-Midwives supports *Senate Bill 212 – Genetic Testing - Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023)*. The bill prohibits carriers that offer life insurance, long-term care insurance, and disability insurance policies or contracts from discriminating against individuals based on genetic tests.

ACNM supports this legislation because an individual's decision about whether to seek genetic testing should not be based on fear of discrimination by insurers. If someone is afraid of discrimination from a life, long-term care, or disability insurer, they may forgo genetic testing. Some couples or individuals seek genetic testing before becoming pregnant, as they want to determine the risk of passing a genetic disorder to a child. Other individuals may seek genetic testing to assess risk of breast or ovarian cancer. Decisions about genetic testing should be made by individuals, in consultation with their providers. Maryland has already made the policy decision to prohibit health insurance carriers from engaging in this practice and ACNM believes that the prohibition should now be extended to disability, life and long-term care insurance carriers.

We ask for a favorable report on this legislation. If we can provide any additional information, please contact Michael Paddy at mpaddy@policypartners.net.

2023 MOTA SB 212 Senate Side FAV.pdf

Uploaded by: Michael Paddy
Position: FAV

Maryland Occupational Therapy Association

PO Box 36401, Towson, Maryland 21286 ♦ mota-members.com

Committee:	**Senate Finance Committee**
Bill Number:	**Senate Bill 212**
Title:	**Genetic Testing - Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023)**
Hearing Date:	**February 8, 2023**
Position:	**Support**

The Maryland Occupational Therapy Association (MOTA) supports *Senate Bill 212 – Genetic Testing - Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023)*. This bill will prohibit life Insurance, long-term care insurance, and disability insurance carriers from denying or limiting coverage based on whether the applicant has undergone genetic testing and prohibiting these types of insurance carriers from canceling a policyholder for undergoing a genetic test. The bill also prohibits carreirs from using a genetic test or the results of a genetic test in a way that would limit, deny, cancel or increase the coverage.

MOTA wants to remove barriers to people obtaining disability and long-term care insurance. Such coverage is essential in supporting people being able to live as indendently as possible. Maryland law already prohibits using health insurance using genetic testing to discriminate against enrollees. This prohibition should be extended to other types of insurance.

We ask for a favorable report. If we can provide any further information, please contact Michael Paddy at mpaddy@policypartners.net.

Maragakis SB 212 Witness Testimony 2-8-23.pdf

Uploaded by: Nicholas Maragakis

Position: FAV

SB212
Nicholas J. Maragakis, M.D.
February 8, 2023

My name is Nicholas J. Maragakis, M.D., I am a Professor of Neurology at Johns Hopkins University and serve as the Medical Director of the Johns Hopkins ALS Clinical Trials Unit and the Center for ALS Specialty Care. I also have a laboratory that studies ALS and have been caring, almost exclusively, for patients with ALS for over 20 years.

Amyotrophic Lateral Sclerosis is a neurodegenerative disease with no known cure. It slowly and relentlessly robs individuals of their strength, speech, swallowing, and eventually their ability to breathe—almost uniformly resulting in death within 2-5 years.

ALS was traditionally thought of as a "sporadic" disease—with no known genetic links. Over the last 25 years, however, over 30 genes associated with ALS have been identified. Therefore, we now estimate that 10% of patients with ALS carry these disease-causing genes in their families. One can imagine the tremendous physical and emotional burden carried by individuals with ALS as well as their family members. This is particularly notable because ALS patients have a 50% chance of passing on these ALS disease genes to their children. It is cruel enough that they carry these burdens but for them not to be able to obtain insurance seems particularly cruel.

As a neurologist, we have important reasons to perform genetic testing on patients. First, it tells us something about their particular disease, in this case ALS. ALS patients with some genetic forms of ALS may have a faster or slower course of the disease. Knowing these genetic subtypes can help us advise them on prognosis and medical management. Secondly, genetic testing can tell us about risks to other family members. Understanding those risks can help individuals with family planning. Finally, and this is my hope for the future, we as a community have now developed gene therapies specifically targeting certain ALS causing mutations—providing hope for those individuals affected by ALS. These gene therapies are now being used in patients harboring those specific genes—a powerful reason to know one's genetic background. Excitingly, we are now looking to treating individuals with known ALS mutations before they develop any symptoms—creating a future for them without the physical and emotional burdens of this terrible disease.

Testimony In Support of SB 212 - HB 155 - Senate F

Uploaded by: Rich Ceruolo

Position: FAV

PARENT
ADVOCACY
CONSORTIUM

February 8, 2023

Maryland Senate
11 Bladen St.
Annapolis, MD. 21401

<u>In Support of SB 212 / HB 155</u>: Genetic Testing Protection Act of 2023

Members of the Maryland Senate's Finance Committee.

We are an organization of military and non-military families with over 1500 members and support our local non-profits that fill necessary roles in our non-profit support and services networks. We fully support SB 212 / HB 155 and the enhanced protections that it brings to our families and children.

Family finances as it relates to all types of insurance is a hotly debated topic in our communities for families of children with disabilities, year after year. Short- and long-term care, as well as insurance other types of policies (and their deductibles) that cover the care for our ourselves and our children are wildly expensive, and a lingering point of enormous emotional and financial stress for so many of our families.

Parents are often forced to spend precious time on the telephone with insurance companies to fight for the coverage that they and their children were promised when their insurance companies sold them coverage. But the goal posts shift quite often for our coverages, policy deductibles and policy premiums. Just when you meet a policy standard, they move the goal posts again and force families to jump through even more hoops just to get essential coverage for care, therapies and equipment that were previously covered. Things are that essential and very necessary for the short- and long-term care of a family member.

That just wrong on so many levels, and I dare say immoral. To treat any of our children and families in this manner is unconscionable but it happens every day in our state. Please work to strengthen the existing genetic protection laws, and deny the insurance companies something else that they can weaponize to use against our families and our children. Let us deny them the ability to use our genetic profiles against our families. Please vote to protect our family's short & long term coverages, as well as our family's long term financial stability. We ask the committee to please support SB 212 and return a favorable report. Thank you for your time, and for considering our testimony today.

Mr. Richard Ceruolo
Public Policy Director | richceruolo@gmail.com
Parent, Lead Advocate and Director of Public Policy Parent Advocacy Consortium
https://www.facebook.com/groups/ParentAdvocacyConsortium

CPD support for SB 212 - Genetic Testing.pdf

Uploaded by: Steven Sakamoto-Wengel

Position: FAV

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STATE OF MARYLAND
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CONSUMER PROTECTION DIVISION

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February 8, 2023

To: The Honorable Melony Griffith
Chair, Finance Committee

From: Steven M. Sakamoto-Wengel
Consumer Protection Counsel for Regulation, Legislation and Policy

Heather Forsyth, Deputy Director
Health Education and Advocacy Unit

Re: Senate Bill 212 – Genetic Testing – Prohibitions on Disability, Life and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023) (SUPPORT)

The Consumer Protection Division of the Office of the Attorney General and the Division's Health Education and Advocacy Unit (HEAU) support Senate Bill 212, sponsored by Senator Klausmeier. Senate Bill 212 extends the protections of current law at Ins. Article § 27-909, which prohibits an insurer, nonprofit health plan, or health maintenance organization from using a genetic test, genetic information, or a request for genetic services to affect a health insurance policy or contact. This bill extends these prohibitions to issuers of life, disability, or long-term care coverage so the issuer may not deny or limit coverage under these contracts or policies based on genetic tests, information, or services.

We share the advocates' concerns that, if consumers fear being denied insurance based on the results of genetic testing, that consumers will instead forego the testing. Genetic testing may be relevant to an individual's health care or lifestyle decisions and may be used to trace ancestry. Genetic testing is also critical to research into curing or treating diseases or developing therapeutic medicines. However, just as Maryland and the federal Genetic Information Nondiscrimination Act prohibit denying health insurance to individuals based on genetic testing, these genetic tests should not also be used to deny an individual the ability to obtain disability, life and long-term care insurance.

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Maryland is not alone in offering its residents consumer protections for genetic testing. Florida recently passed a law for policies starting or renewing after January 1, 2021, which states insurers (including life, disability, and long-term care insurers), in the absence of a diagnosis of a condition related to genetic information, cannot require or ask for genetic information or use genetic test results to deny, limit, or cancel coverage or set different premiums based on genetic information. http://laws.flrules.org/2020/159. (Florida does allow a life or long-term care insurer to consider a *diagnosis* in the medical record, even if the diagnosis was made with the results from a genetic test.)

We do, however, have concerns about some of the definitions in SB 212. For example, page 3, lines 20-21 defines "Genetic Test" as having the meaning set forth in § 27-909 of the Insurance Article. That section defines "Genetic Test" as "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." Although we believe that the definition is broad enough to encompass direct-to-consumer (DTC) genetic tests such as 23 and me or Ancestry.com, the Division wants to ensure that discrimination based on DTC tests is prohibited as well.

Further, Senate Bill 212, on page 4, line 2, prohibits discrimination based upon "genetic information" or a "request for genetic services" without defining those terms. Although those terms are defined in section 27-909 of the Insurance Article, the Division is concerned that applying that definition of "genetic information," which covers information obtained *for diagnostic and therapeutic purposes* at a time when the individual was asymptomatic for the disease, arguably could exclude DTC tests obtained for other purposes. Additionally, § 18-120 of the Insurance Article contains yet a different and inconsistent definition of "genetic information," expressly providing for genetic information that is *not obtained for diagnostic and therapeutic purposes.* We believe that, at a minimum, the Finance Committee should consider using SB 212 as a vehicle for ensuring that the definitions in the Code are consistent, when intended. Moreover, § 18-120 of the Insurance Article already addresses use of genetic testing by long-term care carriers, and this bill would be inconsistent with that law. The two will need to be reconciled.

Despite those concerns, the Consumer Protection Division and HEAU believe that Senate Bill 212 would help to protect Maryland citizens from discrimination based upon the results of genetic testing and respectfully requests that the Senate Finance Committee return a favorable report on Senate Bill 212.

cc: The Honorable Kathy Klausmeier
Members, Finance Committee

DOCS-#229695-v1-SB_212_Genetic_Testing_OPPOSE.pdf

Uploaded by: Matthew Celentano

Position: UNF

The League of Life
and Health Insurers
of Maryland

15 School Street, Suite 200
Annapolis, Maryland 21401
410-269-1554

February 8, 2023

The Honorable Melony Griffith
Chair, Senate Finance Committee
3 East
Miller Senate Office Building
Annapolis, MD 21401

Senate Bill 212 – Genetic Testing – Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023)

Dear Chairman Griffith,

The League of Life and Health Insurers of Maryland, Inc. respectfully **opposes** *Senate Bill 212 – Genetic Testing – Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023)* and urges the committee to give the bill an unfavorable report.

It is critical to understand that underwriting is a fundamental principle that keeps insurance affordable. A life insurer has only one opportunity to evaluate risk before a policy is issued and remains in place for *decades* or more. Once a policy is in place, an insurer cannot cancel it or raise premiums because of subsequent health information or test results. Proper risk classification ensures the solvency of insurers and their ability to pay claims for all policyholders. For this reason, it is very important that life insurers have access to accurate and complete information about an applicant's health, including their full medical record, which may include genetic information and family medical history. It is also important to note that no life insurance company would ever request that a potential beneficiary take a genetic test. These are also voluntary products Marylanders choose to purchase.

Although genetic testing is relatively new, underwriting based on family history is a long-standing practice in Maryland and in all other states. **No other state prohibits underwriting based on family medical history**.

An unintended consequence of SB 212 could be adverse selection, which occurs when an applicant has information—such as genetic information—that increases their risk, but they do not disclose that information to the insurer. This results in the insurer assigning the applicant to a lower risk pool than it would if it had all relevant information. Adverse selection may lead to increased premiums for *all* risk classes and decreased availability of coverage. To avoid adverse selection, there must be a level playing field of information between the applicant and the insurer.

Advances in genetic science are improving health care in America, by giving doctors a better picture of their patients' true medical conditions. These advances improve doctors' ability to treat their patients; they also empower consumers to better control their health and their lives overall. To the extent that genetic testing provides the opportunity for a patient to undergo preventive or ongoing medical care to address a previously unknown condition, insurers may incorporate these results into their underwriting to benefit policyholders.

League members are committed to a robust and competitive insurance market that offers a variety of products that are affordable and meet consumers' insurance needs. Life insurance companies have been able to provide affordable coverage because applicants have shared with consent their complete medical records. It only makes sense that if a life insurance company is going to make a long-term promise, it knows an applicant's true health condition.

Maryland consumers have long benefitted from the accuracy, transparency, and confidentiality in the underwriting process. Prohibitions such as those contained in SB 212 would result in higher prices and fewer choices for Maryland consumers.

Maryland has a robust marketplace that enables competition and affordable options. Life insurance continues to be the most utilized retirement security approach, and SB 212 has the potential to upset the market in such a fashion that Marylanders that rely on their affordable life insurance product for long term financial peace of mind for themselves and their families might find more limited choice of products.

For these reasons, the League urges the committee to give Senate Bill 212 an unfavorable report.

Very truly yours,

Matthew Celentano
Executive Director

cc: Members, Senate Finance Committee

MD SB 212 ACLI Comments.pdf

Uploaded by: Michelle Foster

Position: UNF

Financial Security for Life

Michelle Carroll Foster
Regional Vice President, State Relations
202- 624-2457 t
michellefoster@acli.com

February 8, 2023

The Honorable Melony Griffith
Chair, Senate Finance Committee
Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401

Re: Opposition for SB 212 – Genetic Testing Protection Act of 2023

Dear Chair Griffith and members of the Senate Finance Committee,

I write on behalf of the American Council of Life Insurers (ACLI) to express our opposition to Senate Bill 212.

The American Council of Life Insurers (ACLI) is the leading trade association driving public policy and advocacy on behalf of the life insurance industry. 90 million American families rely on the life insurance industry for financial protection and retirement security. ACLI's member companies are dedicated to protecting consumers' financial wellbeing through life insurance, annuities, retirement plans, long-term care insurance, disability income insurance, reinsurance, and dental, vision and other supplemental benefits. ACLI's 280 member companies represent 94 percent of industry assets in the United States. In Maryland, ACLI's 238 member companies represent 95 percent of the life insurance industry.

Each day, life insurers pay out $35.4 million in life insurance and annuities to Maryland families and businesses, helping Marylanders secure the things that matter most through all stages of life. Our mission is to financially protect families by embracing opportunities to issue coverage to as many consumers as possible.

With respect to Senate Bill 212, it is critical to understand that underwriting is a fundamental principle that keeps insurance affordable. A life insurer has only one opportunity to evaluate risk before a policy is issued and remains in place for decades or more. Once a policy is in place, an insurer cannot cancel it or raise premiums because of subsequent health information or test results. Proper risk classification ensures the solvency of insurers and their ability to pay claims for all policyholders. For this reason, it is very important that life insurers have access to accurate and complete information about an applicant's health, including their full medical record, which may include genetic information and family medical history.

Although genetic testing is relatively new, underwriting based on family history is a long-standing practice in Maryland and in all other states. An unintended consequence of Senate Bill 212 could be adverse selection, which occurs when an applicant has information—such as genetic information—that increases their risk, but they do not disclose that information to the insurer. This results in the insurer assigning the applicant to a lower risk pool than it would if it had all relevant information. Adverse selection may lead to increased premiums for all risk classes and decreased availability of coverage. To avoid adverse selection, there must be a level playing field of information between the applicant and the insurer.

Advances in genetic science are improving health care in America, by giving doctors a better picture of their patients' true medical conditions. These advances improve doctors' ability to treat their patients; they also empower consumers to better control their health and their lives overall. To the extent that genetic testing provides the opportunity for a patient to undergo preventive or ongoing medical care to address a previously unknown condition, insurers may incorporate these results into their underwriting to benefit policyholders.

ACLI members are committed to a robust and competitive insurance market that offers a variety of products that are affordable and meet consumers' insurance needs. Life insurance companies have been able to provide affordable coverage because applicants have shared with consent their complete medical records. It only makes sense that if a life insurance company is going to make a long-term promise, it knows an applicant's true health condition.

Maryland consumers have long benefitted from the accuracy, transparency, and confidentiality in the underwriting process. Prohibitions such as those contained in Senate Bill 212 would result in higher prices and fewer choices for Maryland consumers.

Thank you for your time, and please do not hesitate to contact me with questions.

Sincerely,

Michelle Carroll Foster

Michelle Carroll Foster

Cc: Members of the Senate Finance Committee

2009 MIA Genetic Testing Report.pdf

Uploaded by: Andrew Tress

Position: INFO

MARYLAND
INSURANCE
ADMINISTRATION

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

DECEMBER 2009

For further information concerning this document, please contact:

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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.[1]

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.[2]

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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[1] 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.

[2] 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.[3] 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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[3] 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.[4]

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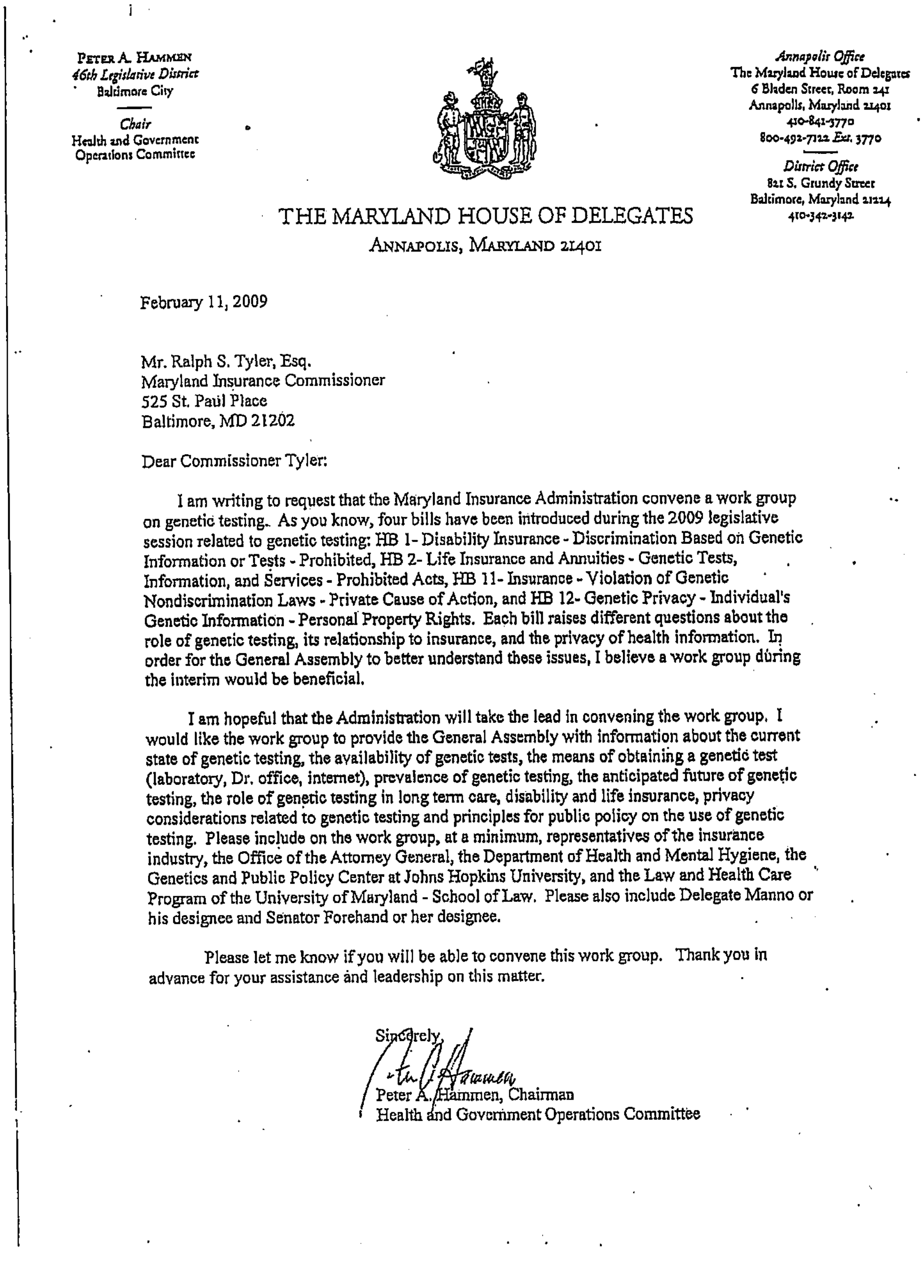
[4] According to the industry, asymmetry of information may occur because of direct-to-consumer marketing of tests or the lack of comprehensive communication between physicians which prevents medical records from always being complete.

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

THE MARYLAND HOUSE OF DELEGATES
Annapolis, Maryland 21401

Annapolis Office
The Maryland House of Delegates
6 Bladen Street, Room 241
Annapolis, Maryland 21401
410-841-3770
800-492-7122 *Ext.* 3770

District Office
821 S. Grundy Street
Baltimore, Maryland 21224
410-342-3142

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,

Peter A. Hammen, Chairman
Health and Government Operations Committee

PETER A. HAMMEN
46th Legislative District
Baltimore City

Chair
Health and Government
Operations Committee

THE MARYLAND HOUSE OF DELEGATES
ANNAPOLIS, MARYLAND 21401

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RECEIVED
MARYLAND INSURANCE ADMIN.
2009 MAR -4 PM 3:00
APPEALS CLERK

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

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

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
California Cal. Ins. Code § 10143(a)	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 Colo. Rev. Stat. Ann. § 10-3-1104.7	Proper use of genetic testing information. Colo. Rev. Stat. Ann. § 10-3-1104.7(3)(b) Specific, written, informed consent required. Colo. Rev. Stat. Ann. § 10-3-1104.7(10)(a)	Health care insurance, group disability, and long-term care	Definition of "genetic testing" Colo. Rev. Stat. Ann. § 10-3-1104.7(2)(b)
Connecticut Conn. Gen. Stat. Ann. § 38a-816	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. Conn. Gen. Stat. Ann. § 38a-816 (19)	Health insurance (includes long-term care and disability income)	Definition of "genetic information"Conn. Gen. Stat. Ann. § 38a-816 (19)
Delaware Del. Code Ann. tit. 16 § 1220, Del. Code Ann. tit. 16 § 1221(a), Del. Code Ann. tit. 16 § 1224(a)(10)	No person shall obtain genetic information about an individual without first obtaining informed consent from the individual. Del. Code Ann. tit. 16 § 1221(a)	General applicability — not specific to insurers.	Definition of "genetic characteristic" Del. Code Ann. tit. 16 § 1220(1) Definition of "genetic information" Del. Code Ann. tit. 16 § 1220(2) Definition of "genetic test" Del. Code Ann. tit. 16 § 1220(3)
District of Columbia D.C. Code Ann. § 2-1402.31 D.C. Code Ann. § 2-1401.02	Rules for eligibility, premium adjustments, and contribution amounts based genetic information prohibited. D.C. Code Ann. § 2-1402.31 (3) Genetic test cannot be required. D.C. Code Ann. § 2-1402.31 (4)	Health insurer (does not specifically exclude long-term care, disability)	Definition of "genetic information" D.C. Code Ann. § 2-1401.02 (12A-i) Definition of "genetic test" D.C. Code Ann. § 2-1401.02 (12B)
Florida Fla. Stat. Ann. § 626.9706, Fla. Stat. Ann. § 626.9707, Fla. Stat. Ann. § 760.40	DNA analysis may be performed upon informed consent. Fla. Stat. Ann. § 760.40(2)(a) Use of DNA analysis in decision to grant or deny insurance coverage. Fla. Stat. Ann. § 760.40(3)	General applicability, including insurers	Definition of "DNA analysis" Fla. Stat. Ann. § 760.40

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. Fla. Stat. Ann. § 626.9706, Fla. Stat. Ann. § 626.9707	Life and disability	
Georgia No applicable provisions.			
Hawaii No applicable provisions.			
Idaho Idaho Code § 39-8302, Idaho Code § 41-1313	Discrimination based genetic test or private genetic information prohibited. Idaho Code § 41-1313.	Life insurance, annuities and disability insurance	Definition of "DNA" Idaho Code § 39-8302(2) Definition of "DNA sample" Idaho Code § 39-8302(3) Definition of "genetic analysis" or "genetic test" Idaho Code § 39-8302(5)
Illinois 410 ILCS 513/10, 410 ILCS 513/20	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." 410 ILCS 513/20(a) 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. 410 ILCS 513/20(b)	Accident and health	Definitions of "genetic information," "genetic testing," and "genetic test" 410 ILCS 513/10
Indiana Ind. Code Ann. § 27-8-26-1 et seq.	Insurer may not: Require genetic test Ind. Code Ann. § 27-8-26-5, Inquire about results of genetic test Ind. Code Ann. § 27-8-26-6, Cancel or refuse to issue or renew coverage Ind. Code Ann. § 27-8-26-7, Limit benefits or set premiums based on genetic Ind. Code Ann. § 27-8-26-8 When genetic test results may be considered Ind. Code Ann. § 27-8-26-9	Accident and sickness (life, disability income insurance specifically excluded)	Definition of "genetic screening or testing" Ind. Code Ann. § 27-8-26-2

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

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
Maryland Md. Code Ann. Insurance § 27-208(a)(3)	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. Md. Code Ann. Insurance § 27-208(a)(3) For long-term care insurance: limitations on requesting a genetic test Md. Code Ann. Insurance § 18-120 (B)(4); permissible use of genetic test results or genetic information Md. Code Ann. Insurance § 18-120 (C)	Life and annuities, long-term care insurance	For long-term care insurance: Definition of "genetic information" Md. Code Ann. Insurance § 18-120 (A)(2) Definition of "genetic test" Md. Code Ann. Insurance § 18-120 (A)(4)
Massachusetts Mass. Gen. Laws Ann. ch. 175 § 120E	Refusal to issue or renew, charging an increased rate, and restrictions on coverage length based on genetic test results prohibited, with certain exceptions. An applicant cannot be required to undergo a genetic test as a condition to issue or renew policy. Standards for requesting genetic information on an application and the use of that information if the insured chooses to provide it.	Life	Definitions of "genetic information" and "genetic test"
Mass. Gen. Laws Ann. ch. 175 § 108I	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. Subsection (c): Standards for requesting genetic information on an application and the use of that information if the insured chooses to provide it.	Disability/LTC	Subsection (a): definitions of "genetic information" and "genetic test"

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

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
Nevada Nev. Rev. Stat. Ann. § 629.111, Nev. Rev. Stat. Ann. § 629.121, Nev. Rev. Stat. Ann. § 629.131, Nev. Rev. Stat. Ann. § 629.151	Cannot obtain any genetic information of a person without first obtaining the informed consent of the person or the person's legal guardian. Nev. Rev. Stat. Ann. § 629.151	Insurers who provide coverage for long-term care and disability income excluded from applicability of chapter.	Definition of "genetic information" Nev. Rev. Stat. Ann. § 629.111 Definition of "genetic test" Nev. Rev. Stat. Ann. § 629.121
New Hampshire N.H. Rev. Stat. Ann. § 141-H:1, N.H. Rev. Stat. Ann. § 141-H:5	Use of genetic information in writing a type of insurance coverage other than life, disability income, or long-term care insurance prohibited. N.H. Rev. Stat. Ann. § 141-H:5	Life, disability income and long-term care insurance	Definition of "genetic testing" N.H. Rev. Stat. Ann. § 141-H:1(IV)
New Jersey N.J. Stat. Ann. § 17B:30-12	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. N.J. Stat. Ann. § 17B:30-12(f)	Life, health, credit life, annuities, and disability income insurance	Definitions of "genetic characteristic," "genetic information," and "genetic test" N.J. Stat. Ann. § 17B:30-12(e)(2)
New Mexico N.M. Stat. Ann. § 24-21-2 et seq,	Use genetic analysis, genetic propensity or genetic information in the ordinary conduct of business. N.M. Stat. Ann. § 24-21-3(D), N.M. Stat. Ann. § 24-21-4(C), N.M. Stat. Ann. § 24-21-5(C)	Life, disability and long-term care insurance	Definitions of "DNA," "gene products," "genetic analysis," "genetic information," "genetic propensity," and "genetic testing" N.M. Stat. Ann. § 24-21-2
New York N.Y. Ins. § 2615; N.Y. Civ. Rights § 79-*l*	Written consent for genetic test and notification of adverse underwriting decision required. N.Y. Ins. § 2615(a) and (e)	Insurers	Definition of "genetic test" N.Y. Civ. Rights § 79-*l*(1)(a) "Genetic test" shall have the same meaning as defined in section [N.Y. Civ. Rights § 79-*l*] of the civil rights law." N.Y. Ins. § 2615(i) Definition of "genetic predisposition" N.Y. Civ. Rights § 79-*l*(1)(b)
North Carolina N.C. Gen. Stat. § 58-58-25	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. N.C. Gen. Stat. § 58-58-25	Life	Definition of "sickle cell trait" N.C. Gen. Stat. § 58-58-25 Definition of "hemoglobin C trait" N.C. Gen. Stat. § 58-58-25

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

State/ Citation	Underwriting Limitations	Applicability of Underwriting Limitations	Definitions
South Dakota No applicable provisions.			
Tennessee Tenn. Code Ann. § 56-7-207	Refusal to issue or deliver any policy of life insurance based on possession of sickle cell trait or hemoglobin C trait prohibited. Tenn. Code Ann. § 56-7-207(a)	Life insurance	Definition of "hemoglobin C trait" Tenn. Code Ann. § 56-7-207(b)(1) Definition of "sickle cell trait" Tenn. Code Ann. § 56-7-207(b)(2)
Texas Tex. Ins. Code Ann. § 546.001 et seq.	Genetic information or a refusal to submit to genetic testing may not be used to deny, limit, cancel, nonrenew, or increase premiums policy premiums. Tex. Ins. Code Ann. § 546.052 Testing permitted under certain circumstances; use of results for inducement prohibited; genetic testing is allowed upon written consent. Tex. Ins. Code Ann. §546.051 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. Tex. Ins. Code Ann. § 546.053	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" Tex. Ins. Code Ann. § 546.001(1) Definition of "genetic characteristic" Tex. Ins. Code Ann. §546.001(2) Definition of "genetic information" Tex. Ins. Code Ann. § 546.001(3) Definition of "genetic test" Tex. Ins. Code Ann. § 546.001(4) Definition of "RNA" Tex. Ins. Code Ann. § 546.001(5)
Utah Utah Code Ann. § 26-45-102, Utah Code Ann. § 26-45-104	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. Utah Code Ann. § 26-45-104(1)	Health care insurance (excludes replacement of income)	Definition of "genetic analysis" or "genetic test" Utah Code Ann. § 26-45-102(4)(a) Definition of "private genetic information" Utah Code Ann. § 26-45-102(7)(a)
Vermont Vt. Stat. Ann. tit. 18 § 9331 et seq.	Prior written authorization and informed consent required. Vt. Stat. Ann. tit. 18 § 9332(d) Underwriting decisions or conditioning a policy on take a genetic test or the results of a genetic test prohibited. Vt. Stat. Ann. tit. 18 § 9334(a)	Life, health, disability, long-term care	Definition of "genetic information" Vt. Stat. Ann. tit. 18 § 9331(6) Definition of "genetic testing" Vt. Stat. Ann. tit. 18 § 9331(7)

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. Vt. Stat. Ann. tit. 18 § 9331(7). Vt. Stat. Ann. tit. 8 § 4724	Insurer	
Virginia Va. Code Ann. § 38.2-508.4, Va. Code Ann. § 38.2-3431, Va. Code Ann. § 38.2-3436	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. Va. Code Ann. § 38.2-508.4(B) Genetic information shall not be treated as a preexisting condition in the absence of a diagnosis. Va. Code Ann. § 38.2-3431(B) Health insurers may not determine eligibility for coverage or charge higher premiums on the basis of health status-related factors. Va. Code Ann. § 38.2-3436(A) (C)	Accident and sickness (excluding disability income)	Definitions of "genetic characteristic," "genetic information," and "genetic test" Va. Code Ann. § 38.2-508.4(A) Definition of "health status-related factor" includes genetic information. Va. Code Ann. § 38.2-3431 Definition of "preexisting condition exclusion" Va. Code Ann. § 38.2-3431
Washington No applicable provisions.			
West Virginia No applicable provisions.			
Wisconsin Wis Stat. Ann. § 631.89	Restrictions on use of result of genetic tests. Wis Stat. Ann. § 631.89(3)	Life or income continuation insurance	Definition of "genetic test" Wis Stat. Ann. § 631.89(1)
Wyoming Wyo. Stat. Ann. § 26-19-107	Genetic information, in the absence of a diagnosis of a condition related to the genetic information, may not be treated as a preexisting condition. Wyo. Stat. Ann. § 26-19-107(f), (g) Restrictions on use of genetic testing information. Wyo. Stat. Ann. § 26-19-107(m)	Group disability	Definition of "health status related factor" Wyo. Stat. Ann. § 26-19-107(a)

Appendix 3: Meeting Minutes

Workgroup on Genetic Testing

June 22, 2007
Meeting Minutes

Participants:

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

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 alleviate further confusion.

Workgroup on Genetic Testing

July 20, 2009
Meeting Minutes

Participants:

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

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

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 5th meeting.

Workgroup on Genetic Testing

September 17, 2009
Meeting Minutes

Participants:

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

UNIVERSITY OF MARYLAND
SCHOOL OF MEDICINE

September 16, 2009

Ms. Beth Sammis
Workgroup on Genetic Testing
Maryland Insurance Administration
200 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

20 Penn Street, HSF-II, Room S-114 • Baltimore, Maryland 21201 1075 • 410 706 6256 • 410 706 6262 fax
sliggett@medicine.umaryland.edu • [illegible]

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
Miriam G. Blitzer, Ph.D.
John Dodge, M.D.
Deborah Hellman
Michael Hickey
May Jung, M.D.
Mary Kivlighan, J.D.
Jennifer Kulynych, J.D., Ph.D.
Honorable Roger Manno
Bruce Margolis, DO
Matt Palmer
Susan Panny, M.D.
Lisbeth Pettingille
Debbie Rivkin
Kimberly Robinson
Timothy Smith
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.[1] 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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[1] 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 consumer 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 INDVIDUAL, 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 EXPERTIES 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

ACLI
Financial Security. For Life.

The League of
Life and Health Insurers
of Maryland

AHIP
America's Health
Insurance Plans

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

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Governor

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Lt. Governor

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Commissioner

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Date: **February 8, 2023**

Bill # / Title: **Senate Bill 212 – Genetic Testing - Prohibitions on Disability, Life, and Long-Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023)**

Committee: **Senate Finance Committee**

Position: **Letter of Information (LOI)**

The Maryland Insurance Administration (MIA) appreciates the opportunity to provide the Committee with information regarding Senate Bill 212.

If enacted, Senate Bill 212 will place certain prohibitions on the use of genetic information and genetic testing by carriers offering life insurance, long-term care (LTC) insurance, and disability insurance. Specifically, under a new § 27-909.1 to Insurance Article,[1] carriers issuing these products would not be permitted to: 1) deny or limit coverage based solely on whether an applicant or policyholder has undergone genetic testing; 2) prohibit a policyholder from undergoing genetic testing; or 3) use a genetic test, the results of a genetic test, genetic information, or a request for genetic services to affect a life insurance, LTC insurance or disability insurance policy in any way, including rejecting, denying, limiting, cancelling, refusing to renew, or increasing the rates.

Section 27-909 currently imposes many of the same prohibitions on insurers, non-profit health service plans, and HMOs, but expressly exempts life insurance, LTC insurance, and disability insurance from those prohibitions. In 2009, the Maryland General Assembly asked the MIA to convene a Workgroup on Genetic Testing to explore the use of genetic information and genetic testing in disability insurance and life insurance. The MIA issued a report in December, 2009 to summarize the findings and recommendations of the Workgroup. Although some of the information in the report is outdated due to recent advancements in medicine and genetic research, many of the issues examined by the Workgroup remain relevant to the discussion of Senate Bill 212, including providing the background and rationale for why § 27-909 of the Insurance Article currently exempts life insurance, LTC insurance, and disability insurance from the

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[1] All statutory references herein are to the Insurance Article, Maryland Annotated Code.

prohibitions on the use of genetic testing and genetic information. A copy of the complete report is attached to this letter of information.

As the Committee considers SB 212, for context, the MIA notes that there are important differences between the three types of insurance impacted by Senate Bill 212 and the products (primarily health insurance products) that are currently subject to the prohibitions under § 27-909 of the Insurance Article. Life insurance, LTC insurance, and disability insurance are products intended to be of long duration that remain in force and guaranteed renewals as long as premium is paid. For these types of insurance, insurers have only one opportunity to evaluate and price a risk that is being insured for decades to come because, *once issued, premium cannot be adjusted based on changes in the health or risk profile of the individual insured.*[2]

Given that, for these three types of long-duration insurance products, the applicant's health status, as well as their individual and family health history, are not only permissible considerations during underwriting, but are often critical considerations in deciding whether to insure the applicant and, if so, what to charge for that insurance.[3] From the standpoint of fiscal responsibility and solvency, it is imperative that carriers price these products correctly at the outset to assure that the amount of premium collected over the life of the policy (and all policies in the aggregate) will be sufficient to cover the claims that are typically made decades after the policies were issued. That requires carriers to consider life expectancy, longevity and an individual's mortality or morbidity risk based on relevant predictive information – which includes information about the individual's health status, health history, family history and, where it exists, genetic information and genetic testing results.

In the current Maryland market, to the MIA's knowledge, no authorized carrier requires or requests applicants to undergo genetic testing as part of the underwriting process. However, where medical underwriting occurs, to the extent results for genetic testing exist in the medical record, carriers writing in the Maryland market do consider this information if it is relevant to their underwriting standards. Doing so actually allows insurers to be more precise and inclusive in underwriting. For conditions with a genetic component, the results of genetic testing may improve an applicant's risk profile. For example, for certain conditions, there may be only a small number of cases where the condition is inherited, while the majority of cases develop without a genetic cause. If such a condition is part of the applicant's family history, a genetic test result showing the absence of gene is a favorable underwriting consideration that helps the consumer in the underwriting process. Consequently, while the MIA appreciates that one of the goals of Senate Bill 212 appears to be to protect individuals with genetic conditions from adverse underwriting decisions, the MIA is concerned that prohibiting insurers from considering the results of genetic tests is more likely to be detrimental to individuals, particularly those who may have a family history of diseases

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[2] For these products, changes in rates can only be made with respect to an entire class based on the underwriting and loss performance of that entire class. This excludes individual life insurance contracts where premiums cannot exceed the maximum in the policy. Typically, the premiums charged at issue may start out lower than increase up to the maximum rates in later years. Accurate underwriting and pricing of individuals according to accurate loss assumptions helps avoid class based rate changes.

[3] Not all policies in these lines of business are medically underwritten. For example, group life insurance products offered through employers and in place during the term of employment typically do not require medical underwriting for certain levels of coverage.

that have both genetic and non-genetic risk factors. Additionally, since life, LTC, and disability insurers would still be permitted to underwrite individuals based on information in the medical record that does not have a genetic component, Senate Bill 212 could be viewed as discriminating against those who have diseases that lack a genetic cause.

The MIA also notes that if life insurers, LTC insurers, and disability insurers can no longer consider genetic information or testing results, insurers will likely respond by raising premium rates overall, and by making underwriting standards more stringent for health conditions that lack a genetic cause. Genetic information and testing results, where available, allow insurers that issue long-duration policies where the risk is priced based on long term predictions of life and health status to be more precise in their underwriting and pricing. Insurers have expressed concern about the impact of being unable to identify or price coverage for someone who receives genetic test results and, based on concerns about those results, applies for coverage. Where genetic information and test results already exist within the medical records, prohibiting an insurer from utilizing that data when it is directly relevant to underwriting criteria makes loss predictions less accurate both with respect to the individual being underwritten and, ultimately, with respect to the class as a whole; while carriers cannot change an individual's premium after issuance of these kind of policies, if losses for the class of individuals is higher than projected, the rates can be change for the class, leading to premium increases for all individuals. Ultimately, removing the current ability of carriers that issue these products blunts the instruments used to underwrite and price equitably and is likely to result in more declinations and higher pricing as a substitute for more precise loss assessment.

At present, the MIA is not able to assist the Committee to quantify the potential impact on rates, because, to the MIA's knowledge, only one state, Florida, has passed legislation that imposes similar (but not quite as broad) prohibitions as those contained in Senate Bill 212 on the life, LTC and disability market. That legislation, which was enacted in 2020, is too new to assess. We note, however, that legislation in Florida is pending that would narrow the prohibitions and allow for consideration of existing genetic information and test results in an applicant's medical records.

From a technical perspective, the MIA notes that the bill conflicts with the terms of § 18-120 of the Insurance Article. Section 18-120 includes certain prohibitions related to genetic tests and genetic information for LTC insurance that are not wholly consistent with new § 27-909.1, but, importantly, permits the use of genetic tests by carriers of LTC insurance to deny or limit coverage, or change the rate for insurance so long as "the use is based on sound actuarial principles." An amendment would be necessary to either § 18-120 or § 27-909.1 to resolve this conflict.

Additionally, the terms "carrier," "genetic services," and "genetic information" are used in § 27-909.1 of the bill, but are undefined, and these words have several different definitions within the Insurance Article. Finally, the use of the word "solely" on page 3, line 28, would have the effect of allowing a carrier subject to § 27-909.1 to use genetic information if it is part of, but not the only reason for, the denial. If this is not the intention, the sentence should be re-drafted.

Thank you for the opportunity to provide this letter of information. The MIA is available to provide additional information and assistance to the Committee.

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Maryland
DEPARTMENT OF HEALTH
Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Acting Secretary

February 8, 2023

Senator Melony Griffith
Chair, Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, Maryland 21401

RE: SB 212 - Genetic Testing – Prohibitions on Disability, Life, and Long–Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023) – Letter of Information

Dear Chair Griffith and Committee Members:

The Maryland Department of Health (MDH) is submitting this letter of information for Senate Bill (SB) 212 - Genetic Testing – Prohibitions on Disability, Life, and Long–Term Care Insurance and Educational Materials (Genetic Testing Protection Act of 2023). SB 212 requires that on or before April 1, 2024, MDH shall review and update materials relating to genetic testing in order to educate the public on: 1) the benefits of genetic testing; and 2) the impact of genetic testing on access to life insurance, disability insurance, and long–term care insurance policies and contracts.

In its current scope of work, MDH does not regulate genetic testing or provide educational materials on genetic testing that would be relevant to the benefits of genetic testing, its impact on access to life insurance, disability insurance, and long-term care insurance policies and contracts. The Office for Genetics and People with Special Health Care Needs (OGPSHCN) within MDH works to ensure a comprehensive, coordinated, culturally effective, and consumer-friendly system of care that meets the needs of Maryland's children and youth with special health care needs and their families. OGPSHCN achieves this mission by administering programs and providing information related to Newborn Metabolic Screening, birth defects, sickle cell disease, and congenital heart disease. As part of this work, OGPSHCN conducts surveillance on birth defects and ensures referral to genetic centers for children who screen positive for certain genetic disorders tested for at birth through Maryland's Newborn Metabolic Screening program.

Regulation and dissemination of information about genetic testing largely occurs at the federal level rather than state level. A number of federal agencies regulate and/or provide information on genetic testing, including protections offered by the Genetic Information Nondiscrimination Act (GINA) of 2008.[1] These include the National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration, Centers for Medicare and Medicaid Services, and Federal Trade Commission.

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[1] Genetic Information Nondiscrimination Act (GINA) of 2008

If you would like to discuss this further, please do not hesitate to contact Megan Peters, Acting Director of Governmental Affairs at megan.peters@maryland.gov or (410) 260-3190.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.
Acting Secretary