NATIONAL COUNCIL OF INSURANCE LEGISLATORS
LIFE INSURANCE AND FINANCIAL PLANNING COMMITTEE
OKLAHOMA CITY, OKLAHOMA
DECEMBER 6, 2018
DRAFT MINUTES

The National Council of Insurance Legislators (NCOIL) Life Insurance & Financial Planning Committee met at The Renaissance Oklahoma City Convention Center Hotel in Oklahoma City, Oklahoma on Thursday, December 6, 2018 at 10:15 a.m.

Representative Deborah Ferguson of Arkansas, Chair of the Committee, presided.

Other members of the Committees present were:

Sen. Jason Rapert (AR)
Asm. Ken Cooley (CA)
Rep. Matt Lehman (IN)
Rep. Joseph Fischer (KY)
Rep. Steve Riggs (KY)
Rep. Edmond Jordan (LA)
Sen. Dan "Blade" Morrish (LA)
Rep. George Keiser (ND)
Sen. Jerry Klein (ND)
Asm. Andrew Garbarino (NY)
Asw. Pamela Hunter (NY)

Other legislators present were:

Rep. Sam Kito (AK)
Rep. Larry Liston (CO)
Sen. Gary Dahms (MN)
Sen. Paul Utke (MN)
Sen. Paul Wieland (MO)
Asm. Kevin Cahill (NY)
Rep. Marcus McEntire (OK)
Rep. Tom Oliverson, M.D. (TX)
Rep. Joe Schmick (WA)

Also in attendance were:

Commissioner Tom Considine, NCOIL CEO
Paul Penna, Executive Director, NCOIL Support Services, LLC
Will Melofchik, Legislative Director, NCOIL Support Services, LLC

MINUTES

After a motion was made by Sen. Jerry Klein (ND) and seconded by Asm. Andrew Garbarino (NY) to waive the quorum requirement, the Committee unanimously approved the minutes of its July 12, 2018 meeting in Salt Lake City, UT upon a motion made by Rep. George Keiser (ND) and seconded by Rep. Joseph Fischer (KY).

EXAMINING PRESIDENT TRUMP'S EXECUTIVE ORDER ON RETIREMENT PLANNING

Michael Kreps, Esq., of Groom Law Group, stated that President Trump signed an Executive Order (EO) in September of this year on retirement security. The September EO was actually President Trump's second on retirement security, but the first to actually propose a path forward on affirmative new policy regulations. The September EO actually does not implement anything but rather calls on certain federal agencies to perform certain actions. The September EO contained three key issues that President

Trump wanted to focus on, the first being to encourage retirement savings, particularly through employer provided plans and small businesses by liberalizing the rules related to how employers can pool their resources and participate in a single plan.

The September EO also seeks to streamline some of the federally required disclosure and notice requirements and consider moving to an electronic based delivery system. Finally, the September EO directs the Treasury Department to look at retirement accounts and the rules related to required minimum distributions. Those rules essentially state that at 70.5 years of age, you must start taking money out of your retirement account, and the rules have not been updated in a long time. Many people are still working at age 70.5 and there is a desire to potentially change the age threshold account in order to let the money stay in a tax-favored retirement account longer. Mr. Kreps stated that the Department of Labor (DOL) and Treasury have not moved forward yet with any concrete actions relating to either the disclosure and notice requirements and the RMDs although they are expected to do so at some point in 2019.

However, the Administration has moved forward with a proposed regulation on multiple employer plans (MEPs). The concept of MEPs has been around for a long time and in Oklahoma and this part of the country there are a lot of cooperative plans that essentially have an association that runs an employee benefit plan – whether it's a traditional pension or 401k – and members participate in that plan by virtue of being part of the association. In many cases, it was found that such plans allowed small businesses to provide a benefit that they otherwise would not have been able to provide, both in terms of the level of sophistication needed to run the benefit, particularly with respect to traditional pensions, and in terms of time and energy. It's difficult for owners of a shoe shop to spend time monitoring and overseeing a retirement plan.

Accordingly, the Administration proposed a regulation that is intended to ease up on some of the DOL's prior rulings with respect to MEPs by allowing more people to sponsor and participate in MEPs with the goal of achieving economies of scale, pooling assets, and obtaining efficiencies. The regulation was proposed by DOL (83 Fed. Reg. 53534) a couple of months ago and the comment period closes on December 24. Mr. Kreps stated that in general, the DOL has taken a very restrictive view of who can participate in MEPs, and that was not because of concerns over retirement policy but rather to some concerns on the health side. The Employee Retirement and Income Security Act (ERISA) has broad preemption provisions and in the past there had been arrangements that had been started in states to provide health insurance through Multiple Employer Welfare Arrangements (MEWAs) that had taken advantage of ERISA's preemption provisions to preempt many state health insurance protections and when the premiums collected were not sufficient to pay benefits, the plan essentially disappeared leaving people in a bad position.

Regulatory steps were then taken to prevent that from happening again including the DOL tightening its rules to state that MEPs need to be fairly limited. The Administration, on the retirement side of things, has chosen to do something different and loosen those rules, recognizing that the health plan concerns are not necessarily intended for retirement plans. The Administration has essentially stated that more entities that are legitimate associations can sponsor MEPs. Rules are also sought to be liberalized to allow professional employment organizations (PEOs) to sponsor MEPs. Many PEOs currently sponsor such plans but they never had a set standard.

Mr. Kreps stated that while the proposed rules are a positive development, they do not go very far in the grand scheme of things. There is still a lot more that can be done to liberalize the system and allow more small businesses to provide retirement plans to their employees. The DOL could always expand the rules when it finalizes its proposal after receiving comments, but more importantly, Congress is examining these issues and legislation is expected.

Bruce Ferguson of the American Council of Life Insurers (ACLI) stated that retirement security is an issue that has been brewing for many years and the good news is that we are on the brink of potentially historic legislation passing at a time when it is needed the most. The good news is that Americans are living longer and healthier lives, but the bad news is that a significant percentage of Americans are woefully under-saved for their retirement years which could last up to 30 or more years. It is very important that national policy is now catching up to these issues.

Mr. Ferguson stated that the September EO Mr. Kreps discussed was very important because it sent the right message at the right time – that the Administration was serious about retirement security - but through regulations the Administration can only go so far. Mr. Ferguson stated that the Retirement Enhancement Savings Act (RESA) is a legislative proposal that has been under consideration and development for some time but now enjoys bi-partisan and bi-cameral support. The Act could very well pass the lame duck session of Congress through different vehicles such as a tax-extension piece of legislation or a year-end funding bill. Mr. Ferguson encouraged the legislators present to contact their Congressional delegations to encourage them to adopt RESA.

Mr. Ferguson stated that MEPs would be a key and essential part of RESA. Other key attributes of RESA relate to annuities – the only type of private sector product that can guarantee a lifetime income stream. If RESA were to be signed into law, it would signal to the American population that is trying to save for retirement that they now have options at the federal level for taking advantage of the economies of scale of MEPs and other enhancements regarding auto-enrolling in retirement plans.

Mr. Ferguson also thanked NCOIL for its leadership relating to enhancing the standard of care for annuities through adopting a Resolution opposing the DOL's Fiduciary Rule – sponsored by Sen. Jason Rapert (AR) – NCOIL President. The Fiduciary Rule was the product of the Obama Administration and it sought to impose a Fiduciary standard on all financial sales professionals. Mr. Ferguson stated that even though the Rule had only been partially implemented, we saw the dramatic effect it had on the market. The losers under that rule were the low to moderate income savers that would be deprived of access to advice and to products. The movement away from commission-based sales to fee-based sales would deprive a significant segment of the population of advice and products at a time when the needed it.

Mr. Ferguson stated that there is a movement under way at the Securities and Exchange Commission (SEC) and the National Association of Insurance Commissioners (NAIC) to right-size and enhance the "standard of care" to add additional key consumer protections but in a very responsible way. Mr. Ferguson stated that such action can be done by changes to existing state laws and regulations that deal with annuity suitability requirements. Mr. Ferguson stated that the legislators present should expect to see such legislation introduced in their states soon.

UPDATE ON LIFE INSURANCE INDUSTRY "HOT TOPICS" – AN ACTUARY'S VIEW ON PRINCIPLE BASED RESERVING (PBR) AND VARIABLE ANNUITY RESERVE AND CAPITAL REFORMS

Lisa Kuklinski, Actuarial Consultant, stated that reserves are what life insurance companies put aside to satisfy their future policyholder obligations. Reserves are based on a projection of what the claims and benefits would be. Projections are based on assumptions about mortality, longevity, interest rates, and equity performance. Up until now, the reserve calculation was very formulaic, highly prescribed, static, and interest rates would be locked in over the life of the policy. PBR brings us to a more guided framework which takes into account the unique risks and features of products, even products that don't exist in the marketplace today.

Ms. Kuklinski stated that PBR is important because the older calculations would often be overly conservative which would have an impact on consumers and lead to companies looking to reduce that burden by putting their business into a captive insurance company which reduced transparency and created an unlevel playing field. Ms. Kuklinski stated that there were issues with formulaic reserves being too low but that is countered by practices such as cashflow testing and asset adequacy analysis that actuaries must conduct and sign off on every year to make sure reserves are adequate. PBR "right sizes" reserves by accounting for moderately adverse conditions, product features, and company data.

Ms. Kuklinski stated that PBR for life products is based on the NAIC Valuation Manual 20 (VM 20); VM 21 deals with variable annuities; and VM 31 deals with PBR Actuarial Report Requirements for Businesses Subject to a PBR Valuation. The VM is adopted state by state and there can be some state specific variations. New York's adoption of the VM is still pending[1]. Life insurance VM 20 implementation is already live and in effect, so companies had the first opportunity to introduce it in 2017 with new issues in 2018 and 2019 – there is a three-year implementation period. VM 20 applies to new issues so we will see the impact of it slowly as each year of new issues comes into play and is reserved for under VM 20. Ms. Kuklinski stated that a very limited number of companies implemented VM 20 in 2017, mostly with term products. More companies are starting to bring it in 2018. In terms of implementing PBR and introducing products that incorporate the latest mortality tables, it is a multi-year process. Companies have also made a significant investment in modeling. The VM 20 reserve includes a net-premium reserve, a deterministic single-scenario reserve, and perhaps the most onerous is the stochastic reserve where benefits are projected out over thousands of interest rate and equity scenarios to understand the different dynamics.

Assumption setting is also a key factor because PBR looks at a company's own data for their products and statistical credibility measures and allows them blending with industry experience if needed. Ms. Kuklinski stated that financial reporting under PBR has to do with the analysis and attribution of those reserves. Ms. Kuklinski further stated that in addition to VM guidance, there has also been a significant effort by the industry to comply with PBR such the as American Academy of Actuaries (AAA) implementing the actuarial standards of practice (ASOPs) which set out the standards of professionalism

[1] On Dec. 7, 2018, NY Governor Andrew Cuomo signed into law PBR enabling legislation. The NY DFS promptly responded with an emergency regulation to begin the implementation of PBR to become effective on January 1, 2020 - https://www.dfs.ny.gov/about/press/pr1812101.htm

for the qualified actuary that signs off on the reserves. The AAA also promulgates Practice Notes.

Ms. Kuklinski stated that she sees communication with the state regulator as a very positive benefit of PBR because the disclosure and documentation requirements starts a dialogue. At least 80% of the industry has had at least one or two discussions with their state regulator and that will probably increase going forward. Ms. Kuklinski further stated that under the prior standards – actuarial guidelines 38 and 48 – reserves were well in excess of the economic reserve, what you would hold on a fair value basis. PBR has decreased what we're seeing as the redundant level of reserves that were compelling companies to form captives. Roughly 1/3 of the companies are seeing that reserves are "right-sized", another 1/3 are seeing that reserves are perhaps in excess of the economic reserve but not to the level where they have to seek alternatives, and the remainder are seeing redundancy and that perhaps reserve financing would be pursued.

Ms. Kuklinski stated that VM 21 reform is going to have a very large impact as variable annuity assets for the industry are in the trillions and the reserves associated with the guarantees can be substantial. When the variable annuity framework is implemented – it has not been passed yet – it will impact both new and in force business. Variable annuities were the first foray into PBR with the actuarial guidelines 43 standard and the reserve that was introduced over 10 years ago and the industry recognized some flaws in that it allowed for diversity in company practice and an un-level playing field. The reserve framework was complicated and there is a standard scenario that is meant to be a flood but ended up dominating a lot of the time which had impacts on company's hedging programs and caused some counter-intuitive movements.

Ms. Kuklinski stated that she was part of an industry effort that worked on two quantitative impact studies looking at different possibilities to change the reserve framework and what has been proposed is still being drafted but the industry seems to be comfortable with it as the standard scenario truly exists to catch outliers and company's that have very different properties and assumptions. Having industry policyholder behavior assumptions will need to be refreshed and having economic assumptions that are consistent with VM 20 for life insurance. Ms. Kuklinski stated that VM 31- the actuarial report – has been evolving over time. Each year, it is updated to standardize the format, eliminate redundancies and clarify certain issues.

With regard to next steps, Ms. Kuklinski stated that almost every company is looking at different ways to accelerate underwriting to use big data and public information to take the underwriting process, which is very onerous today, and provide consumers with their policies faster. The problem is that there are not mortality tables which reflect that type of underwriting, so the industry is looking to come up with guidance and find what is appropriate and that is something where as we see experience emerge and become credible, it will be used over time. State-specific guidance from states such as New York and how that will impact products will also need to be examined. Ms. Kuklinski stated that fixed indexed annuities have experienced a lot of growth and those reserve standards will need to be re-examined, probably in 2021. Ms. Kuklinski closed by stating that the industry has welcomed the changes she discussed and appreciates the opportunity to have a dialogue over issues such as creating a level playing field and right-sizing reserves. The opportunity to discuss these issues with regulators provides for a stronger solvency framework. PBR will undoubtedly evolve but Ms. Kuklinksi stated that industry believes it will stand the test of time.

DISCUSSION ON THE USE OF GENETIC TESTING IN INSURANCE UNDERWRITING

Prof. Anya Prince of the University of Iowa College of Law stated that she will be discussing research she has done under a National Institutes of Health grant that looks at whether or not we should have regulation on insurer use of genetic information in life, long term care, and disability insurance. Prof. Prince stated that in 2008, the Genetic Information and Nondiscrimination Act (GINA) was passed which prohibits discrimination on the basis of genetic information with respect to health insurance and employment. In many ways we never got to see what the impacts of that were because just two years later the Affordable Care Act (ACA) was passed which changed risk classification in the health insurance realm. Accordingly, we missed out on the data on what it means to have insurers not take into account genetic information.

Prof. Prince stated that GINA does not cover life, long term care or disability insurance so the question becomes should we ban insurer's use of genetic information? There are two sides to the argument. From the social perspective, it is very important to have access to insurance, to have privacy, and to assuage fear of genetic discrimination. There is empirical evidence that people do not participate in genetic research and do not get clinically recommended genetic testing for fear of how that information will be used by life, long term care and disability insurers. Therefore, there are people who, if they had undergone that testing, could take preventive measures to better their health. Failure to do so is of course bad for them, but also bad for the insurers who insure them.

Prof. Prince stated that she believes some regulation is needed in this area. On the other hand, from the insurer perspective, genetic tests can tell you a lot about risk factors so in order to assess actuarially fair premiums the argument is that insurers need to be able to access information about predictive genetic tests, and avoid adverse selection whereby someone may know they are at risk for breast cancer by means of a genetic test but the insurer cannot take that information into account. Prof. Prince stated that much of her research deals with how to balance those two perspectives. More succinctly, should we have a GINA 2.0 that expands beyond just health information? The issue has been brought up at the federal level, but it has never gained traction.

Prof. Prince stated that regulatory options fall into two main categories right now: ban life, LTC and disability insurer use of genetic information, or permit it. Prof. Prince stated that she believes there should be some regulation so if choosing between those options she would choose to ban insurer use. However, there are other regulatory options abroad that can serve as models for how to regulate, not ban, insurer usage. Some policy constraints that have been implemented in other countries are monetary limits and independent review. For monetary limit policy, such policy states that under a certain threshold amount, insurers are not able to take into account genetic information, i.e. any life insurance policy under $500,000 cannot take into account predictive genetic information. Prof. Prince stated that such a policy is a balance that helps to mitigate fears about adverse selection because you can model out the impact up to that monetary limit, make adjustments to those pools, and avoid consumers taking out huge policies with knowledge of certain genetic information.

Independent review policy constraints consist of an independent body viewing the actuarial evidence of a genetic condition and listing out those genetic conditions that meet actuarial review. That is an interesting policy because most genetic information at

this point in time is not particularly helpful in assessing risk. There are very few genetic conditions that actually have high enough penetrants and will happen to be important to life insurers. Accordingly, there is a disconnect between when somebody goes to get a genetic test and is scared off because in their informed consent documents it says "life insurers may use this information…", and the actuality that the information the insurer obtains through the genetic test will be helpful to them is quite slim.

Accordingly, some countries look at each genetic condition piece-by-piece. Modeling currently being done by the Society of Actuaries (SOA) and the Canadian Institute of Actuaries lists 13 genetic conditions that are relevant for life insurers. Being able to review those conditions and state that those are the conditions life insurers can take into account would give much clearer information for genetic counselors, genetic researchers, the medical community, and advocacy groups to tell patients in order to help assuage the fear patients have of insurers using all genetic information with no restrictions.

Insurers in the U.K. have voluntarily agreed to bar use of most predictive genetic test results. Such policy started in 2000 and every 3 to 5 years it has been renewed. Prof. Prince stated that in her discussions with insurers and genetic researches in the U.K., they agree that the policy is working well. In October 2018, the voluntarily policy was converted into an open-ended code where there will continuously be such a policy. There is a monetary limit: over 500,000 £ for life insurance; and there is also an independent review. The only genetic test that has been approved by the relevant government body in the U.K., which is actually now defunct because there were not enough applications, is Huntington's disease for life insurance policies.

Prof. Prince stated that another important consideration is how to define genetic information. GINA defined the term to include family medical history so if a state implemented a law relating to genetic information and life insurance, using the GINA definition would have a much greater impact on the life insurance filed as opposed to only including predictive genetic testing or genetic testing that is both predictive and diagnostic. It is also important to keep up to speed with scientific advancements in the understanding of both risk and the preventive measures available. As those treatment advancements happen, it will change the risk classification and change the risk somebody has. There are also issues to consider as to the implications across different lines of insurance in terms of how prohibiting the use of genetic testing in underwriting would impact life insurers vs. LTC insurers and disability insurers. Additionally, considering who has the information relating to a genetic test is important: a policy constraint that comes into play there is one that states insurers can obtain information about a genetic test that is currently in someone's medical records or done pursuant to direct-to-consumer testing. Also important to consider is the question of whether insurers can require someone to undergo genetic testing.

Rep. Keiser stated that Prof. Prince did not talk about any policy constraints directed toward the consumer. Rep. Keiser stated that based on his parents and siblings living well into their 80s, he believes he is a good risk for insurers and would therefore like a cheaper premium and be able to sign a waiver that permits insurers to use genetic testing information. Rep. Keiser stated that he believes good risks like he and his siblings are subsidizing the unhealthy population. Accordingly, Rep. Keiser asked when will we give power back to consumers? Prof. Prince stated that in the U.K., the code that was developed with the insurers allows individuals to give information about

favorable genetic information. Also, Oregon law states that favorable genetic information cannot be used for inducement of insurance and the reasoning behind that is if you allow people to use favorable genetic information, insurers may then backend into who has an adverse genetic test. Using Huntington's disease as an example, you have a 50/50 chance of having that mutation if you have a family history of it. If those with a negative test can show it to the insurer, the insurer will assume that everyone who did not show the test has the disease. Rep. Keiser stated that such a policy is adverse selection in reverse and is not fair.

Rep. Joe Schmick (WA) asked Prof. Prince if she has actually seen rates go down, or only go up when the genetic information is used. Rep. Schmick stated that it seems a way to drive rates up under the guise of being an appropriate risk, but those that do not have the risk would not see the benefit. Prof. Prince stated that it is delicate balance. In the U.K., where for 18 years insurers have not been able to take into account predictive genetic information, they have not seen much adverse selection. There has been some raising of premiums but to the extent that they have tried to model it, they have not seen much of an increase. There has been other modeling done by the Canadian Institute of Actuaries and the SOA to take into account that premiums will go up and there is some risk-pooling will happen with people with more favorable genetic information will be subsidizing people without such information. The modeling varies depending on what assumptions you put into the model.

Prof. Prince stated that she believes it comes down to whether or not we expect that we should have some pooling. There are other factors that have been legislated that acknowledge the actuarial impact but are not permitted to be used by life insurers such as race and being the victim of domestic violence. The underlying questions become: does genetics fall into those categories? Do we want to encourage people to get tested? If that is a social value that we hold dear, we are going to have to take on some adverse selection and have an increase in premiums across the board.

Rep. Schmick asked again if Prof. Prince has seen rates go down and the consumer benefit during her research. Prof. Prince stated she has not seen a specific example of a consumer providing the information and the rate going down, but actuaries in the room and Mr. Margolis may be able to answer that question.

Bruce Margolis, Chair of the ACLI's Risk Classification Cmte., stated that the process of underwriting for individual life, LTC, and disability insurance is really a risk assessment process. It is looking for the risk of that individual for premature death or an early claim for disability or LTC. That process involves the use of a variety of pieces of information, including whether an individual is at risk for certain diseases like cardiovascular diseases, or has already developed diseases that may have a mortality or morbidity impact. By law, insurers must classify similar risks similarly and that approach is balanced against what we might call a standard life-expectancy risk pool. The key benefit of that approach is that it enables insurers to make products available at the lowest price to as many people as possible. If you have everyone in one pool like in a group insurance product, the price for individuals who are really healthy is higher than what they might get on the open market and they are subsidizing others in the pool who are not as healthy.

Unlike health insurance, P&C insurance, and disability insurance, life insurance underwriting is a one-time event. When an individual knows something about

themselves that the insurer doesn't there is a risk that the individual will be inappropriately placed in a better-than-should-be risk classification pool. That is the concept of adverse selection. If you have too many unhealthy people in a healthy pool, that will skew the results over time and prices will go up resulting in healthy people leaving the pool altogether.

Starting in 1865 when Gregor Mendel discovered the laws of basic genetics, it took almost 100 years until the biochemistry of DNA was elucidated. Since then, there has been both baby steps and big steps, the most recent big step being the completion of the human genome sequence in 2003 at a cost of hundreds of millions of dollars in both the public and private sectors. Now the cost per genome to sequence is less than $1,000. With that efficiency comes more research and it is almost every day there are new research findings related to genetics.

Additionally, a DTC genetic testing market now exists where consumers can go on the internet, obtain a kit, submit some of their saliva, and get an analysis of their DNA. A lot of that is recreational and done for ancestral purposes but there are some companies that will give you some genetic risk profile based on the sample given. That is a potential source for adverse selections for insurers as individuals may discover they have a predisposition for a certain disease and they then purchase a life, LTC or disability insurance policy.

Dr. Margolis stated that it is important to note that these are complex issues that have social, ethical, medical and business aspects to them. There are different types of genetics tests. A diagnostic genetic test can confirm a clinically suspected disease such as cystic fibrosis. A predictive genetic test determines risk for a particular disorder by determining "penetrants." Screening genetic testing can be done with prenatal and newborn screening. A field of pharmacogenomics exists where geneticists look at an individual's genetic makeup to determine whether a drug is suitable for the individual and what the safest and most effective dose is. Tumor analysis exists, and is one of the fastest growing genetic fields, whereby the genetic markers in a tumor, not the patient, are examined to guide treatment. Pharmaceutical companies have been able to create biologics that target that abnormal genetic profile and have achieved significant improvements in cancer survival.

Dr. Margolis stated that several different types of people are involved with these issues: insurers, physicians and researchers, consumers, and legislators and regulators. Insurers want to sell insurance but want to ensure that it is a fair product and a level playing field exists where they understand and appropriately risk-classify individuals. Issues that have come up surrounding genetics include privacy, confidentiality, disclosure, utilization, discrimination, and genetic exceptionalism – the concept that genetic information is different from other medical information. Dr. Margolis stated that from his medical perspective, genetic information is medical information, but others may see it from a different perspective.

In 1990, the Ethical, Legal and Social Implications (ELSI) Program was established by the National Human Genome Research Institute and was charged with researching the ethical, legal and social implications of genetic research for individuals, families and communities. The insurance industry is heavily regulated and is bound by a number of consumer privacy protections. Insurers also must notify individuals of the reason for an

adverse underwriting decision and give them the chance to correct that if there is some misinformation involved.

Dr. Margolis stated that a number of states have genetic-based laws and while a lot of the laws are centered around privacy, authorization, and confidentiality issues, some relate directly to the topic being discussed today. In Vermont, VT 8 V.S.A. § 4724 prohibits insurers from using genetic testing information unless the insurer can show reasonable anticipated experience that the risk is related to that particular genetic issue. In Massachusetts, MA 175 § 120E restricts the industry's use of genetic information but allows an insurer to use the information if it is based on sound actuarial principles or reasonable expected experience. Dr. Margolis stated that the economic success of voluntary insurance products hinges on a level playing field of information for appropriate and fair risk categorization. Insurers need to properly understand the risk to appropriately price the risk. The field of genomics is also growing at a very fast rate as the industry is starting to see more and more genetic information on insurance applications – some of which is not pertinent to the risk but the fact that it is there is clear. The clinical use of genetic information remains limited but is expanding at a rapid pace and will become commonplace over time. How long that will take is not clear as getting from research to clinical use is extensive, but we will get there and there will be a tipping point along the way where it will take place significantly. Dr. Margolis closed by stating that public discourse such as the conversation today needs to continue and consider all stakeholders in order to maintain wide access to competitively priced insurance products while protecting individual privacy rights and allaying concerns over proper information use.

Rep. Deborah Ferguson (AR) – Chair of the Committee – asked if all of the labs conducting the DNA and genetic tests are subject to FDA regulations. Dr. Margolis stated that there are two realms of control: the Clinical Laboratory Improvement Amendments (CLIA) controls the lab itself; individual tests can be FDA approved. As an example, with a company such as 23 & Me, their lab can seek CLIA approval and in 2013 the FDA told them to cease and desist because the tests they were using had not gone through FDA-certification. 23 & Me is now back with a very limited, FDA-approved genetic test. Prof. Prince stated that the regulations often look at the clinical and analytical validity of the tests and don't necessarily look at clinical utility which is really the question relating to risk. Accordingly, there is information that could be clinically useful on an aggregate level but depending on the individual and their gender, ethnicity and family history, the clinical utility changes.

Further, there is a debate in other countries (less so in the U.S.) about research findings. Should research findings be able to be used? In the U.S., if a research finding is returned to an individual for treatment purposes, it is supposed to re-certified in a CLIA lab but there is some debate among researches about what that means for treatment. There is theoretically a way that there could be information that falls outside of those regulatory schemes that could come into play. Dr. Margolis stated that there are tests that come to clinicians. For example, there is a test to determine how well an individual metabolizes or doesn't metabolize a certain type of anticoagulant. Dr. Margolis thought that clinicians were going to use the test because it has been validated but the clinical utility of the test has not been found. Similarly, insurers have to look at the risk utility of certain information: just because something is there does not mean it relates to morbidity and mortality. Rep. Ferguson stated that with the implementation of personalized medicine, policy should be avoided that would inhibit people getting the care they need.

Rep. Keiser stated that both Dr. Margolis and Prof. Prince have given the indication that we are early in the stage of development of these procedures, but he does not agree with that. As a member of a fully integrated healthcare delivery system, 2 years ago they implemented a major project throughout the system for genome testing for cancer patients. There are very individualized treatment programs and the success rate is phenomenal. At the same time they did that, a program was enacted for the public that risk testing could be done and as a board member he got it for free. The program that he got was not primitive and very scientific. What intrigued him was the reaction of other board members when their tests came back with markers that were not favorable and their first comment was that they have to increase their life insurance. Accordingly, Rep. Keiser stated that the technology that Dr. Margolis and Prof. Prince describe is not as primitive as they suggest and that its use is more widespread than they think, particularly among those who can afford such tests to make very important decisions that can have a big impact on reserves and the industry.

Prof. Prince agreed that the technology and testing is indeed rapidly improving and increasing but what we are very early in understanding is the question of what exactly the risk is. As an example, when the BRCA gene was first discovered which relates to breast and ovarian cancer risk, early estimates were that the penetrants of that marker measured out to be a likelihood of 60% to 80% of getting that type of cancer. That is because we have an ascertainment bias because the families tested first were the ones with the most penetrants. That estimate has lowered over the years and now we're down to around 60%. Accordingly, we're not there yet to where we can truly pinpoint what the risk information means. We're starting to get more people tested, but as more tests occur, that complicates the factors. So what do you do if you get a positive BRCA test and you have a very large family and none have breast or ovarian cancer? What does that mean for an insurer? Those are questions that still need to be answered and that reinforces the point that more people should get tested so that we can better understand the risk. If we have it so that such information can be used by insurers and people are scared of getting tested, that is a problem.

Prof. Prince acknowledged the concern of people taking genetic tests and then quickly going to get a policy if the test showed unfavorable results. Now, the practice is that if you go to get a single predictive genetic test often times genetic counselors will suggest that the consumer secure their insurance first. The Canadian Institute of Actuaries made an assumption that 75% of people who test positive for 13 genetic conditions will go out and get as much life insurance as they possibly can. Based on that assumption, they found a high impact on premiums. Prof. Prince stated that she does not believe that is accurate because a lot of people cannot afford that much life insurance; and they want it to cover their house to make sure their family is ok, but they don't want to necessarily go out and scam the insurance system. Accordingly, more research is needed to determine changes in insurance purchasing behavior. People are also bad at understanding their risk so if you say you have a 60% increase in risk of breast cancer which means you have a 16% increase in risk over the percentage risk in the general population, you may have people going out and getting more insurance than they need based on odds ratios vs. overall risk.

Dr. Margolis agreed with Rep. Keiser in that the technology is already here and keeps getting better. In terms of utilization, Dr. Margolis looks at 40 to 50 sets of medical records every day and most of them have no genetic testing information, but the

prevalence is increasing. What he sees today is very different from a couple of years ago. Healthcare systems are thinking about how to integrate this into the process of what we are calling personalized medicine and precision medicine. Efforts are underway at the Federal level via the All of Us Research Program which is an effort to gather data from one million or more people living in the U.S. to accelerate research and improve health.

ADJOURNMENT

There being no further business, the Committee adjourned at 11:30 a.m.