NATIONAL COUNCIL OF INSURANCE LEGISLATORS
JOINT STATE-FEDERAL RELATIONS & INTERNATIONAL INSURANCE ISSUES COMMITTEE
2024 NCOIL ANNUAL MEETING – SAN ANTONIO, TEXAS
NOVEMBER 24, 2024
DRAFT MINUTES

The National Council of Insurance Legislators (NCOIL) Joint State-Federal Relations & International Insurance Issues Committee met at The Westin Riverwalk Hotel in San Antonio, Texas on Sunday, November 24, 2024 at 9:00 a.m.

Kentucky Representative Rachel Roberts, Chair of the Committee, presided.

Other members of the Committee present were:

Sen. Justin Boyd (AR)
Rep. Deborah Ferguson, DDS (AR)
Rep. Matt Lehman (IN)
Rep. Brenda Carter (MI)
Sen. Lana Theis (MI)
Sen. Paul Utke (MN)
Rep. Bob Titus (MO)
Sen. Walter Michel (MS)
Sen. Jerry Klein (ND)
Sen. Pam Helming (NY)
Rep. Ellyn Hefner (OK)
Rep. Tom Oliverson, M.D. (TX)

Other legislators present were:

Rep. Stephen Meskers (CT)
Rep. Matthew Gambill (GA)
Sen. Larry Walker (GA)
Rep. Brian Lohse (IA)
Rep. Rod Furniss (ID)
Rep. Peggy Mayfield (IN)
Rep. Bill Sutton (KS)
Sen. Jason Howell (KY)
Rep. Mike Meredith (KY)
Rep. Cherlynn Stevenson (KY)
Sen. Mark Huizenga (MI)
Sen. Hillman Frazier (MS)
Sen. Bill Gannon (NH)
Asw. Catalina Cruz (NY)
Asm. Erik Dilan (NY)
Sen. George Lang (OH)
Rep. Mark Tedford (OK)
Sen. Patty Kuderer (WA)

Also in attendance were:

Commissioner Tom Considine, NCOIL CEO
Will Melofchik, NCOIL General Counsel
Pat Gilbert, Director, Administration & Member Services, NCOIL Support Services, LLC

QUORUM

Upon a Motion made by Rep. Ellyn Hefner (OK) and seconded by Sen. Walter Michel (MS), the Committee voted without objection by way of a voice vote to waive the quorum requirement.

MINUTES

Upon a Motion made by Rep. Deborah Ferguson, DDS (AR), NCOIL Immediate Past President and seconded by Rep. Matt Lehman (IN), the Committee voted without objection by way of a voice vote to adopt the minutes of the Committee's July 18, 2024 meeting.

CONSIDERATION OF NCOIL MODEL ACT IN SUPPORT OF MENTAL HEALTH WELLNESS EXAMS

Rep. Roberts stated that we will start today with consideration of the NCOIL Model Act in Support of Mental Health Wellness Exams (Model), a Model which I am very proud to sponsor. You can view the model on page 330 in your binders and on the website and app. To provide some brief background on where we started and where we are now, we had a great session focusing on mental health parity at our summer meeting last July in Minneapolis. And after that I decided I really wanted to keep the conversation going and hopefully have NCOIL adopt some model policy on the issue. If I'm not mistaken, that conversation last July was the first time in decades that NCOIL really had a session that focused solely on mental health and mental health coverage. That conversation initially started with a bill I sponsored in Kentucky which was very straightforward and simply requires insurance companies to provide coverage for an annual mental health wellness exam that is performed by a mental health professional.

We then decided both at NCOIL and in Kentucky to expand that legislation to include several other related provisions but it became clear the consensus on that was probably not realistic, although I do hope that you all will continue to discuss those issues which were mostly around substance use disorder treatment. So that leads us to today, and I've essentially gone back to the original version aiming to require coverage for an annual mental health wellness exam. Thank you to everyone who has provided feedback on this throughout the past year. This has truly been a collaborative effort and I have indeed incorporated many of the requested changes. In fact, since the model was distributed in the 30 day materials, I made one technical change in the model in Section 4(b)(1) on page 332 to align it with other provisions in the model. I hope that the committee will support this model, and I look forward to the discussion we will have around it today.

David Lloyd, Chief Policy Officer at Inseparable, thanked the Committee for the opportunity to speak and stated that we're a non- partisan, a non-profit organization that works to build a future where mental health policy is advanced and where mental health is treated as a critical piece of overall health. Our main priorities are increasing access to care, addressing our youth mental health crisis, expanding the mental health provider workforce and building a crisis system that gets people the help they need and removes critical burdens that now fall primarily on law enforcement. Inseparable strongly supports moving upstream and helping identify and treat people's mental health and substance use disorder challenges earlier. And therefore, we strongly support efforts to increase access to mental health wellness exams and we thank Rep. Roberts for bringing this model forward. Approximately one in four Americans, about sixty million Americans have a diagnosable mental health condition, but fewer than half are receiving any mental health treatment. And the numbers are particularly stark for youth. Indeed, three in four mental health conditions develop by the age of 24, and approximately 13% of youth ages 12 to 17 have reported experiencing serious thoughts of suicide based on the most recent data.

And alarmingly, one in five of our youth has had at least one major depressive episode in the past year and nearly half of those six million youths, nearly three million, did not receive any help despite having a major episode. Nearly 20% of Americans also have a substance use disorder, yet 90% of Americans don't receive any treatment. And just yesterday there was a report that alcohol related deaths have doubled since the 1980’s. And unfortunately, although teenagers and young adults developing mental health and substance abuse disorders often show significant warning signs, there’s really long delays in getting them the help that they need. For example, when a young person is experiencing symptoms of early psychosis, which often precedes bipolar disorder or diagnosis of schizophrenia, the average time they wait before

receiving any help is 74 weeks, about a year and a half. This is really simply tragic. During this time, young people often become sicker and as time goes by, more difficult and expensive to treat. So, ensuring access to no cost sharing, mental health wellness exams just like physical health is a critical step forward. Indeed, improving affordability is one of the most important parts of mental health wellness exams. States like Colorado, Connecticut, and New Mexico have moved forward with mental health wellness exams because they want to increase affordability and get people hope early before mental health and substance abuse disorders worsen and drive overall physical healthcare costs higher.

And this is because there's overwhelming evidence that individuals with untreated mental health and substance use disorders do drive overall health care costs higher. Milliman found, based on claims data, that people with these diagnosis have between 2.8 and 6.2 times higher physical health care costs depending on the exact diagnosis, yet most receive little or no treatment. These costs also are very high because we're only intervening at very late stages and the results are frequent emergency department visits, hospitalizations, uncontrolled physical health conditions, and very often for many, incarceration, which is extraordinary costly to local and state governments. And this is perhaps not surprising given that when these illnesses are not treated, cognitive functioning is what is impaired so you often see that they are unable to control their physical health and overall well-being. So I urge the committee to take this important step forward of supporting the model. Inseparable is happy to work with legislators in your states to advance this important issue. We also look forward to being engaged in NCOIL next year and beyond on these important issues.

Sen. Bill Gannon (NH) asked what are the costs associated with this, and also, if I go for one mental checkup a year, is that really going to do anything? Mr. Lloyd stated that one visit can help identify early challenges that individuals may have so we can get them services early on when it's much more cost effective to treat these conditions.

Rep. Roberts stated that to add to that, the underlying goal of the model is to normalize mental health care, and also to make sure that patients have someone that they're already in a relationship with so that should they get to a moment of crisis, they know who to call and we're not seeing them so much necessarily at the emergency room and those kinds of things. And then also in states like mine, we want to to help drive mental health providers to the state where we have a shortage so that they can start to build their practices there. As far as cost goes, in Kentucky, if we were to layer this over the state health insurance plan, the maximum cost that we saw would be potentially up to $3 per month per insured.

Hearing no further questions or comments, upon a Motion made by Rep. Ferguson and seconded by Rep. Lehman, the Committee voted without objection by way of a voice vote to adopt the amendment to Section 4. Then, upon a Motion made by Rep. Ferguson and seconded by Rep. Hefner, the Committee voted without objection via a voice vote to adopt the Model, as amended. Rep. Roberts thanked everyone and stated that the model will now be placed on the Executive Committee's agenda for final ratification.

CONSIDERATION OF RESOLUTION IN SUPPORT OF ESTABLISHING CATASTROPHE SAVINGS ACCOUNTS

Rep. Roberts stated that next on our agenda is consideration of the Resolution in Support of Establishing Catastrophe Savings Accounts (Resolution). You can view this in your binders on page 333 and on the website and app. We hope to be voting on this resolution today. We had a great discussion on this resolution at our last meeting. No opposition has been raised but

before we go any further I will recognize Sen. Walter Michel (MS), one of the sponsors of the Resolution.

Sen. Michel stated that 'm proud to sponsor this resolution. Mississippi is one of several states that's enacted legislation for catastrophic saving accounts. Just as someone can prepare for a health savings account (HSA) for expected or unexpected healthcare costs, one can prepare a tax advantage account for natural disasters. This past year obviously, we've seen several hurricanes, storms, floods, and tornadoes, and I think it's a very appropriate time to get behind this type of legislation and I ask for the committee's support of this resolution.

Rep. Lehman, one of the sponsors of the Resolution, stated that if you were at the NCOIL-NAIC Dialogue yesterday, you heard me bring up the scenario of a situation we're seeing now in the marketplace of deductibles moving to a percentage deductible or a very high deductible and actual cash value (ACV) on the roof. And you're creating almost an exclusion in some cases of roof coverage. Give me the opportunity to create something that can backfill that and I think this is the perfect vehicle for that, and allow me to meet those deductibles and meet those criteria. I absolutely support this resolution.

Kevin McKechnie, Executive Director of the Health Savings Account Council at the American Banker's Ass'n thanked the Committee for the opportunity to speak and thanked the sponsors for all of their work on this. When we last met, we had not yet seen what happened in North Carolina and the challenges at the Federal Emergency Management Agency (FEMA). There has been a federal disaster savings account bill introduction that occurred November 12 when newly re-elected Florida Senator Rick Scott introduced a version of a previous bill. Just as a refresher, 10 years ago the late Oklahoma Senator Jim Inhofe introduced a bill that is, I think, the comprehensive standard, which is to say, if a state experiences perils like wildfire or flood or convective storms, you're encouraged to mitigate against those things which you could spend your funds on. And then you're encouraged to remediate if you suffer from that catastrophe in a way that would be very similar to an HSA. In other words, tax advantage contributions to the account. Tax advantage build up of the assets in the account. And then tax advantage disbursements from the account for the things the Internal Revenue Service (IRS) says are either mitigation or remediation. Just like the HSA model. And again, just to refresh, three states have them now - South Carolina, Mississippi and Alabama. Several states have called in between the July meeting and now are saying they are going to introduce them and so we're consulting on that. And there is this federal legislation which will have to be reintroduced next year. Those of you who would like to read it, it is S. 5296. It will not pass this year. It's a flag in the ground, and a marker of things to come.

In July at this Committee's meeting, I was lucky enough to be joined by a friend of mine, Kirsten Trusko, Co-founder of Payments as a Lifeline (PAAL). The way we manage disasters in this country is not with the government, it is with charities first. And so, the proposals for managing disasters in this country include provisions in the disaster savings account policy, which would allow charities to put money in this account so that it could be used for these mitigation questions. The money that they put in would not be taxed advantaged. The reason the charities want these accounts is because there's no better individual verification system than the financial system, the know your customer rules in banking. And so, fraud wouldn't be eliminated, but it would be minimized if we did this. The other thing that's come up is FEMA and the small business administration (SBA) have made informal inquiries about allowing accounts for small business and sole proprietorships. As you know, a small town can't get back on its feet unless the businesses in that town get back on their feet. And so, we're willing to think about that. I haven't thought about that, but it would be something else that the policy you're putting in

place today would contemplate. And I suppose I'll conclude with this. We're not voting on a bill here. We're voting on a concept. The concept would be better preparing Americans by allowing them to save tax free over time and helping them understand that vigilance begins with them, not the government, with them. And that's why HSA's are the powerful tool that they are.

Paul Martin, VP of State Affairs at the National Association of Mutual Insurance Companies (NAMIC), thanked the Committee for the opportunity to speak and stated that first, I want to thank Mr. McKechnie for his ongoing thought leadership on this topic. He and I started this conversation years ago and he was updating me in on what he's been working on for quite some time. I know from our side of the equation from our industry, we are very supportive of this. These accounts do two things. Most importantly, as Mr. McKechnie mentioned, the first thing they do is they allow consumers, your constituents, to save money by putting money into an account tax free to pay for things like deductibles. To pay for things like repairs after a disaster. So, this is not just protection of their property. This is also financial protection for them as well. The second thing they do, and perhaps even more important than the first thing, is that they help us create a culture of preparedness and resiliency in America that we desperately need right now. My social media feed is filled with disaster after disaster. It's not just heartbreaking, and it's not just affecting their lives in terms of their homes, but it also affecting their finances. And so to the extent that we can come up with mechanisms to help them bear that burden, we should. We should be advocates for that. I'm really pleased that NCOIL is taking this up as a resolution and we should continue this conversation down the road.

Sen. Paul Utke (MN), NCOIL Treasurer, stated that we're looking at savings accounts like the HSA's where you've put money in. Let's say you had $10,000 or $15,000 in this account and you never needed to tap into it. How and when would you recoup that money when you sell your property or after 20 years? What's the end game on this?

Mr. McKechnie stated that these are bona fide trust accounts so they're operable as trust accounts under state law. They would be federally regulated. As you put money into your account, if you have to make a disbursement for a resilient roof or new base flood elevation certificate, or you would like storm resilient windows or whatever it might be, whatever is allowable under the IRS code, that spend inures to the value of the structure you're trying to protect. And so, recouping the money just means you're going to keep saving so the HSA model would apply here, meaning as you save money, by the time you get to a health event, if you spend that money to either manage your deductible or manage your recovery and then you go back into the saving mode. And so, the balances do go up and when they come down on distribution they simply go down. Recouping the money requires you to exert the same amount of diligence you used to save the money in the first place to save the same amount of money in the second place. So, no one reimburses you. It is envisioned, however, that these accounts would act just like the HAS's, they'll be an employee benefit as well. And so, while there is a maximum annual contribution into the account under the existing proposals, the distributions from that account can be whatever is required but there are limitations on what can go in because you can't just put an unlimited amount of money in the accounts but there is no limitation on what comes out depending on the scale of the calamity that you experience.

Sen. Utke stated that just for a little clarity, I like this, but I guess we would have to plan as we would downsize our account because let's say you went along and now we've reached an age where we no longer are going to own a home. We'd want that account to be zeroed out, use it for the eligible deductions up to that point. Otherwise, let's say there was $5,000 left in the account and you sold your home, what would happen to that money? Mr. McKechnie stated that I'm being placed in the position of giving unlicensed financial advice, but I will read from the

bills that I know. These are bona fide trust accounts. It means you must nominate a beneficiary. Just like your HSA account has a beneficiary, it would be a disaster savings account and under the current proposals, if you passed away it would become your spouse's account. Under the Sen. Scott bill, they treated a little differently, which is to say, if your surviving spouse nominated a child, for example, as the beneficiary of the account, when those funds transferred to that child, it becomes a taxable moment. But those funds would be available for the child to put in their disaster service account. So, generationally, the difference between the Sen. Inhofe approach and the Sen. Scott approach, the latter allows one generation of tax accumulation, then there's a tax moment, but that money can go into your children's account to protect the home they're in, so zeroed out in a way. The Sen. Inhofe bill is more permissive. It allows those accounts to go generation to generation on the assumption that the cost of repairing the damages are going to go up, not down.

Rep. Lehman stated that at age 65, I can cash out my HSA for anything I want to use it for - can I do the same thing with this? Mr. McKechnie replied, yes. You would pay income tax on that money, but no penalties.

Rep. Ferguson asked if the accounts apply to both commercial and residential properties. Mr. McKechnie stated that Sen. Inhofe bill creates a category of eligible individuals, and it says any eligible individual living in a residence. And so, what they mean is any single family, multifamily, or condominium that is your residence. And it would also apply to renters. It would not apply to commercial structures unless we were able to create an account for, as FEMA and SBA suggested, for a small business.

Rep. Ferguson asked if you have to file a claim to utilize the accounts? Because we'll have big deductibles and to fix broken glass or things like that, it's going to be way less than the deductible. Can you utilize it for those kind of repairs even though you don't file a claim? Mr. McKechnie replied yes, what you can put in the account and what you can use those dollars for in terms of mitigation and remediation act independently of how you treat the insurance product or the insurance triggers.

Rep. Ferguson asked if the account is limited to one primary residence or can it be used for multiple properties? Mr. McKechnie replied the accounts would operate like HSA's in the sense that a person owns them and the coverage they would have would either be for themselves or for a family and that really only applies in the health model. You don't have to have a property and casualty policy in place to be an eligible individual under the proposals so you'd be able to do whatever you wish with that money. So you could apply to two different residential properties.

Rep. Dennis Paul (TX) asked if you can pay your insurance premiums out of the account? Mr. McKechnie replied under the Sen. Inhofe proposal the answer is yes. Under the Sen. Scott proposal, the answer is no. And this is not an unimportant question because Sen. Bob Hackett (OH) asked a flavor of that question in July during this committee's meeting and the point would be if you had a shock increase in the amount of premium you owed, could you use those dollars to cover the delta in it and if that was a favorable amendment, we would certainly accept that. There would be difficulty defining what that meant at the federal level but we were certainly being in favor of that. Now the other way to manage that of course is if you have a shock increase in premium, can you mitigate that increase in premium by increasing your deductible? Because there's no question that you can use those dollars to pay your deductible and so that changes the algorithm, as you're all aware of what the actual product costs. Rep. Paul stated that might allow more people to buy insurance as we talk about how important it is in making

sure that we have insurance. If you're getting pre-taxed dollars you can really save a lot of money by buying insurance even if you take the high deductible on that.

Hearing no further questions or comments, upon a Motion made by Rep. Lehman and seconded by Sen. Utke, the Committee voted without opposition by way of a voice vote to adopt the Resolution. Rep. Roberts thanked everyone and stated that the Resolution will now be placed on the Executive Committee agenda for final ratification.

PRESENTATION ON PATENT PRACTICES IN THE PRESCRIPTION DRUG MARKETPLACE

Rep. Roberts stated that last on our agenda is a presentation on patent practices in the prescription drug marketplace. I do want to note that PhRMA was invited to participate in this session and they were originally scheduled to, but due to scheduling conflicts, they ended up not being able to provide a speaker.

Wayne Brough, Resident and Senior Fellow of Technology & Innovations at the R Street Institute, thanked the Committee for the opportunity to speak as I think it's an important issue that does have significant impacts on the price of healthcare and the price of health insurance and innovation itself in this space of new drugs and new treatments and therapies. I'll start with what are patents, what they do, what they're supposed to do, and where they really are. And they're sort of distinct from a property right on physical property as it's more of a regulatory framework to promote innovation. It takes a lot of capital to produce drugs and get new drugs to market. It's a lengthy process. It can take 12 to 15 years. So there's a lot of investment that goes on. The patent gives the protection of a certain period of exclusivity that allows those drug makers to then be the sole provider in that market and that generates the profits that can support the research and development (R&D) and move forward in that space. At the same time, once the patent is done, that knowledge goes to anyone and that's where the generic drugs come in where they can produce and compete with the original brand name drugs and it tends to lower prices very quickly. If one generic gets into the market, there's about a 20% or 30% percent reduction in price. With two, it comes down to 50% and you can drastically drop if you get five new generics in the market as prices can drop down by 70% or 80%.

So that's the way the market is set up. But what has happened over time is there's been a certain type of amount of gamesmanship that happens and what we're seeing is what we call patent tickets, where you'll have a blockbuster drug and that drug can have up to 100 patents on it. That makes it difficult for anybody to get into that space and compete with that brand name drug. And as these patents sort of protect that drug, you see delays in competition. You see it harder for generics to get into that market and a lot of these patents are not as inventive as the original. There's primary patents and secondary patents. The primary patent is the active ingredient, the chemical that makes the therapy happen. Secondary patents can be anything around that. It could be the manufacturing process. It could be say you change it from a tablet once a day to a twice a day tablet or you change it from a pill to a capsule. All of those things can be patented. And they start to pile on and each one of those provides another extension of exclusivity so you end up with in a situation where we in the U.S. see drugs being delayed further than they are say in Europe where some of these practices aren't allowed, where important new drugs and biologics get into the market much quicker because they're not playing the sort of gamesmanship that we see here in this country in terms of patenting. So first of all, what does this mean? It means it has an impact on innovation because if you are a new drug company and you're trying to compete and find a way to get into the market where a brand name has a patent thicket with hundreds of patents protecting its products, it's hard for you to get into that market. It's hard for you to innovate and provide new products because there's

always a threat of litigation from the brand name manufacturer. And it's a cost on consumers and taxpayers and healthcare providers because all of these things extend the higher prices because you don't really see price cuts in these markets until the generics actually get into the marketplace. And the longer you can delay the generics from getting into the marketplace, the harder it is to innovate and those are costs that are paid by taxpayers, patients and healthcare providers and healthcare programs.

And then again, there's an impact on competitors. If it's hard to get into that market, we're not going to see competition like in other markets in terms of driving prices down and just seeing how the economics play out. You don't see that in a situation where you have these patents. And for instance, Humira, which was a huge blockbuster drug. It had over 100 patents on it and 66% of those patents were filed after U.S. Food and Drug Administration (FDA) approval and it led to $87 billion in additional revenue before the patent ultimately expired. And the generics for that drug were available seven years earlier in Europe than they were here just because of the way the patent system works here. Revlimid is another one where 74% of the patent applications came after the launch of the product. So these are sort of continuation patents that you're not really inventing anything new. In fact, if you issue a continuation patent, you're not allowed to make new additions to the patent. You just say there's a new claim on that old patent. So there's a lot of things that are happening in this space. With Eliquis and Enbrel, it was a seven to ten years delay compared to Europe in getting these things into the market in the U.S. So you have all of these blockbuster drugs and we want to see the brand name manufacturers innovating because they do produce probably the best drugs in the world but when you have all these patents and sort of the gamesmanship that goes on, it makes it difficult for the providers and patients to enjoy the benefits of these and have access to drugs at an affordable price.

There are three things that are big challenges here. These patents and the patent thickets keep drug prices artificially high. That’s the first problem. The second is we delay competition and delay the entry of generics and again, that's an impact on the system of healthcare who has to pay those prices, particularly if you compare how that plays out in the U.S. versus in other countries. And the third area is you actually end up diverting resources away from real R&D to more of a monopoly protection system where you have these patents and if you have a blockbuster drug, you're talking about tens of millions of dollars for every day that patent is extended. So brand name drugs have a strong incentive to put these patents out there to keep these blockbuster drugs in place but when they do that, that's taking resources away from R&D on new and other innovative things so you end up investing more in monopoly protection versus innovation and new therapy. So those are some of the challenges - how do we fix this? I would say there's two things. We want to make sure that when patents are issued, they're issued for real, inventive, novel uses. That's the first thing. The second is, the patent system is not perfect. We get bad patents in the system. So we need a way to find where those weak or invalid patents are and get them out of the system efficiently. So, those are the two most important things we can do, I think, to improve the way the patent system works. And then I would say another area we could look at is sort of promoting clear pathways for generics to get into the marketplace, particularly with biosimilars, which are the more complex drugs. It's not as clear cut as it is with small molecule drugs, which are the older drugs that we all are familiar with. Biologics, they're harder to manufacture. There's a lot of overlapping patents there which are probably really more valid. They're not those where we change it from a tablet to a pill so we need a new patent. These are complex manufacturing issues. But identifying a pathway to get into that space I think is very important in terms of trying to improve the process and make the system work like it's supposed to.

In terms of what's happening in DC on this, the Senate passed the Affordable Prescriptions for Patients Act in the summer and that is one way to get at the patent tickets. This is a bill by Sen. John Cornyn (TX) that was specifically addressing the role of patent tickets and how to get out of that. There's two other bills. The Patent Eligibility Reform Act which I think takes things in the wrong direction by making it harder for competitors to get into the market. That is sort of floating around. It came up for an early hearing and they were hoping it would be done by the end of the year but that has not happened so I think that'll be a live issue in the next Congress. The PREVAIL Act was passed just this past Thursday and again, I think this one takes it in the wrong direction. It makes it harder for a post patent review. There's something called the patent trial and appeal board at the patent office where if there is a problem with a patent, you can take your case to the patent trial and appeal board. It's quicker than the court system. It's effective as you have three patent experts on the board that make the final determination. But the Act actually limits which cases you can bring before this board. So I think that one is in my mind problematic, but it probably will move forward in the next Congress. And there's another one probably moving forward called the RESTORE Act which basically overturns some important U.S. Supreme Court decisions that sort of laid out patent policy. In the past, if you challenge a patent, you could automatically get an injunction issued by the courts. There was an important U.S. Supreme Court decision on eBay which the judges said, "No, you can't automatically do an injunction. You have to follow these processes." The RESTORE Act would overturn that and make it much easier to get injunctions and those injunctions would impede competition in this space. And again, if all the patents are good, maybe that's not an issue but with all these patent thickets and a lot of these unnecessary, non-inventive patents, if you can get an injunction by claiming there's an infringement on a non-inventive patent, I don't think that helps in terms of innovation or moving the ball forward in terms of getting better therapies to the marketplace.

Rep. Roberts stated I'm hoping you can validate whether something I heard in a story was true - where a secondary patent was effectively issued for something like an asthma inhaler but nothing changed with the formulation, just the cap on the inhaler had something like a tab on it that would allow the cap to not fall all the way off when you used the inhaler. Is it accurate to say that extensions of patents are issued based on something as small as that? Mr. Brough replied yes, that does happen and that's a perfect example of the secondary patents and how they're non-inventive and yet they get the same coverage as the first primary innovative patent. And it allows the extension of that exclusivity and keeps competitors out of the marketplace for a longer duration of time.

Rep. Stephen Meskers (CT) stated that in prior years, the U.S. House Ways and Means Committee has reviewed drug pricing, particularly the U.S. versus Europe, and I believe the pricing differential is about three to four times higher in the U.S. for drug prices. And it's the biggest challenge we face as legislators is working to provide affordable healthcare. But right now, we seem to be chasing pharmacy benefits managers (PBMs) but I'm not convinced that once we finish chasing the dollars from PBMs it ends up with our constituents. If we're looking at patent reform as one of the solutions of that differential in pricing between other countries and the U.S., if we tighten up our regulatory reforms, what would you expect the pricing differential to be for the same pharmaceutical drugs between the U.S. and Europe? How close could we get to parity in pricing? Mr. Brough stated it's a little bit complicated because we have drug reimportation restrictions as well, which is another area that's worth pursuing, but I think you would see substantial reductions, particularly in some of the more expensive drugs. And it does vary on some drugs. As I said, once you get competition in the marketplace, once you get more than three generics in that marketplace, you can see 50% to 70% savings on those things. The more expensive biologics are much more complicated and more expensive so you won't see as

much of a drop just because even if you're a generic, it's going to cost more to produce those drugs. But I think you would see probably at least 30% drops in prices at these drugs.

Rep. Meskers stated just to quantify and I know it's a hard number but we're talking 30% if we're at a $300 premium, you'd be talking about a $210 premium instead of a $300 premium. Mr. Brough replied probably for some of the biologics, you're probably in that space. For example, when Humira extended their patents through these thickets it generated an additional $74 billion for the company so those kinds of costs would go away if you got rid of the patent thickets that you see in the market today.

Rep. Tom Oliverson, M.D. (TX), NCOIL President, stated that we've been talking about this issue at NCOIL for a while and I know that it's interesting that Rep. Meskers is asking questions and I'm asking questions but it's actually our U.S. Senators, Sen. Richard Blumenthal (CT) and Sen. Cornyn, that have really led the charge on this for years. And I guess my question is, do you know what the status is of their bipartisan bill? It's passed the Senate. Is the House going to take it up? Is it going to pass? Mr. Brough stated that there are a lot of things happening in the House right now so we're trying to figure that out. I think there is enough interest that we will see that. I will say that the bill that made it out of the Senate was watered down a little. It went after patent thickets and that is still in the bill. There's another practice called product copying where you get drug companies that make changes or they'll introduce a new version of the drug and then go out in the market and urge doctors and providers to just make the change to the new drug. And the bill had some language in it originally where the Federal Trade Commission (FTC) would look at those practices. That part has been stripped out so now it's purely looking at the patent thicket side of things. I do see that as potentially moving forward. There's also a couple of other bills, I think Sen. Peter Welch(VT) has a bill that may move forward that looks at some of these issues. But for now, I would say troubling from my perspective is that at the top of the legislative list are the Patent Eligibility Reform Act and the PREVAIL Act and I think both of those go in the opposite direction and make it even harder to challenge some of these secondary patents that are keeping costs high.

Rep. Oliverson stated again, we've been looking at this issue for years and the reason that I mentioned Senators Cornyn and Blumenthal is because it seems like those are the guys that really have taken this issue on and have taken all the arrows and you know all the attacks and the lobbying and all that stuff and they've been working on this together for years. I don't see anything that we can actually do at the state level to address this, even though it's just crushing our patients and our consumers. And it's one of these lobbying things that just irritates me about our government system where we're just piling dollars in the corner and spontaneously combusting them to prevent something from passing that everybody knows really ought to pass. What can we do at the state level? Mr. Brough stated that patents are in the U.S. Constitution something of a creature of Congress so it is sort of a slight step away to look at what states can do. But obviously, every state can make the point that their Medicare costs or Medicaid costs are higher and let your Representatives and Senators know that it's something that you're hearing at the state level. You're hearing from patients or patient advocates who show that these costs are making it harder for people to keep their prescriptions filled. But it is a challenge. I think the debate has been dominated by Senators Thom Tillis (NC) and Chris Coons (DE) who are very much in the camp of let's make patents as strong as possible and not look at some of these problems with patent thickets. And I think last year, at least for me, it's been frustrating trying to work with them to move these bills forward and some of the problems are that patents aren't just for pharmaceutical companies, it affects all businesses. And there's sort of a tech lash going on in DC where everybody hates big tech and they are very much in

play in this patent dispute over reform and unfortunately, issues that they're taking out on big tech are sort of bleeding over into the healthcare side of things.

Rep. Oliverson stated but do they have the same issues in big tech that we have in the pharmaceutical side of things where you string together essentially 500 patents on one process in an attempt ensnare competition? Because that seems to me to be pretty unique to the pharmaceutical industry. Mr. Brough stated that is very unique to the pharmaceutical industry. In the tech space, everybody has licenses and they basically license with each other, so you don't see this. You don't see patents being used as a way to keep generics out of the market, that kind of thing doesn't happen. But the bigger issue I think is just the way the committees in DC are looking at this. They're getting away from the pharmaceutical aspect and we've been sort of pushing the healthcare impacts and over the last year I've done a lot of work to show the impact on drugs and impacts on patients are something that you should not ignore. But unfortunately, I think it is not the top issue when the people are discussing patent reform.

Rep. Oliverson stated that it's frustrating because I know the manufacturers struggle with it too, because you were talking about Humira and a company could be the beneficiary of a patent thicket on one side and then on the other side their own biosimilars are getting crushed by somebody else. So it's sort of like one day you're the robber, and the next day you're the victim. Mr. Brough stated that the pharmaceutical market itself is kind of interesting because you have all these blockbusters and when their patent goes away, everything changes drastically. So they call it a patent cliff where, say, Humira or any of these drugs, as soon as they get close to that cliff, if they don't have a drug in waiting to take its place as the next blockbuster, the company is going to have a profit drop and then they have to start thinking "well, rather than innovate do I just put all my money in protecting this monopoly through more patents?" And we do see that happening where they're investing in keeping the monopoly on the market longer rather than new innovative therapies that come to market.

Rep. Oliverson stated that the last thing I'm going to say is that this is part of the reason why in Texas we passed a bill last session establishing the Texas Pharmaceutical Initiative, which would allow Texas to basically pursue its own generic equivalents in manufacturing spaces and to explore the possibility of doing that to try to address some of these bad behaviors. It's not just the thicket issue, but people will also engage in essentially hush money payments to prevent a company from bringing a generic to market after they figure out who's going to get the license to produce the drug from the FDA. I think there was a very famous case with a calcium channel blocker that was manufactured by Eli Lilly where they basically successfully kept the generic equivalent off the market for almost a decade even though the patent had expired and there were licenses issued. And the ability to manufacture the drug, they essentially just paid them off to keep the competition out of the market. Mr. Brough replied yes, it does happen. In fact, it's called pay for delay and it's a very common practice where generics will enter these negotiations with brands and decide when they'll get come into the market or whether they'll wait so that is another issue that we do see in the marketplace.

Rep. Brenda Carter (MI) stated that along the same line as Rep. Oliverson, since patents are federally regulated, are you saying that there's nothing the states can do to regulate the cost of drugs? Mr. Brough replied not in the patent space. I'm sure there other things states have the authority to do. For instance, one of the things that happened in the past was, and I think a lot of states have their own laws on whether a generic is an acceptable substitute, this was an earlier fight in the drug space when generics were first coming into the marketplace if doctors recommended a drug, was the generic considered an effective substitute? So there are things that states can look at in terms of drug pricing but patent law, they can't really do anything.

Rep. Carter stated that in Michigan, we are considering a prescription drug affordability board (PDAB) – what are your thoughts on those? Mr. Brough stated that I think looking at these things, all of that adds to the debate and I think that moves the discussion forward in terms of focusing on the inherent issue of drug pricing and that sort of feeds back into the whole dispute about are patents excessively monopolistic and keeping prices higher than the competitive market would? So I would encourage activities like that.

Sen. Justin Boyd (AR) stated that in my other line of work I'm a pharmacist and there has been more than one patent extension which have caused pharmacy colleagues to roll their eyes but what I've observed more is now there's this rebating game, especially with the biologics and biosimilars, where it's the pay to play like I'll pay more dollars in rebates to get on the formulary. Do you have any insight into is it really the patent issue or this rebating issue that is really driving the price of pharmaceuticals? Mr. Brough stated that I think it's both. I would say the patent issue provides that initial period of exclusivity which keeps prices higher than they could be. But then once you have that high price, you have every incentive to do everything you can to keep that price as long as possible and that gives you an incentive to do things like these rebates and getting on the right list. And those are all debates and a lot of that's more FDA related than patent related but those are real, valid issues that need to be addressed as well. Sen. Boyd stated that maybe rebating could be addressed by states. Mr. Brough stated I would think that you have a lot more authority there than in the patent space.

Rep. Meskers stated that the conversations that we've had in the past with importing drugs from other countries, it seems to be what we're talking about, ultimately, is either free trade or managed trade and we're in neither area with pharmaceuticals because the price discrepancies across the world are huge. So is there a solution within the patents or is it a solution within protecting our pharmaceutical industry with a certain level of a premium for R&D in the U.S. to continue their work but to limit the pricing differential between us and the Organization for Economic Co-operation and Development (OECD) countries. It seems to me, if we're dealing at 200% or 300%, we're subsidizing the world in R&D and drugs and the only thing we've been able to figure out at the state level is either some regulatory review of the drugs on the formularies or potentially imported drugs from Canada which are all manufactured either in India and China and they're just priced differently. What are your thoughts on drug importation? Mr. Brough stated that it's a separate issue from patents, but it's a real issue and to some extent you're right that we are choosing to subsidize lower prices in other countries by the way we price our pharmaceuticals and you can make the argument that it provides the resources for the innovation and keeps us as a leader in this industry but at the same time, you should be aware of the fact that you're doing it at the cost of higher drugs for Americans who need prescriptions.

ANY OTHER BUSINESS

Rep. Roberts stated that in response to the terrible storms that have hit several states the past few months, I do think it's a good idea to have FEMA and other related parties interact with NCOIL next year to discuss how they've responded to the storms and specifically how the National Flood Insurance Program (NFIP) is working and whether any reforms may be needed.

And as a brief point of personal privilege, this is my last NCOIL meeting and I just wanted to say thank you to everyone. This has really been one of the most enriching portions of my time in public office. Thank you to the NCOIL staff for all of your work. I would also personally just like to take this opportunity to thank the legislators that I've gotten to work with and who have been so generous in helping me. And thank you to all of my Kentucky friends and colleagues and to

the interested parties who are here to make sure that we understand all points of view. This is a great collaboration. I really do believe that we do good work and that this is the best of legislation because it really is well vetted and well discussed. It has been an absolute privilege to be part of this.

ADJOURNMENT

Hearing no further business, upon a motion made by Rep. Carter and seconded by Sen. Utke, the Committee adjourned at 10:15 a.m.