SENATE FINANCE COMMITTEE
Full Committee Hearing

"Lower Health Care Costs for Americans: Understanding the Benefits of the Inflation Reduction Act"

September 17, 2024 – 10:00 AM

OVERVIEW

On September 17, the Senate Finance Committee held a hearing titled, "Lower Health Care Costs for Americans: Understanding the Benefits of the Inflation Reduction Act." During the hearing, Members and witnesses discussed out-of-pocket (OOP) expenses, pre-existing conditions, premium tax credits, step therapy, prior authorization, price negotiation, pharmacy benefit managers (PBMs), Part D premium demonstration project, formulary placement, small molecule and large molecule drugs, patents, generics and biosimilars, research and development (R&D), competition, insulin, commercial insurance, drug shortages, corporate earnings, preventive care, accountable care organizations (ACOs), orphan drugs, ACA plan value, and innovation incentives.

OPENING STATEMENTS

- Chairman Ron Wyden (D-OR)
- Ranking Member Mike Crapo (R-ID)

WITNESS PANEL

- Ms. Judy Aiken – Retired Registered Nurse; Arthritis Patient
- Dr. Jeanne Lambrew Ph.D. – Director of Health Care Reform and Senior Fellow, Century Foundation
- Dr. Rena Conti, Ph.D. – Dean's Research Scholar and Associate Professor, Questrom School of Business, Boston University
- Ms. Kirsten Axelsen – Nonresident Fellow, American Enterprise Institute (AEI); Senior Policy Advisor, DLA Piper
- Mr. Theo Merkel – Senior Research Fellow, Paragon Health Institute; Senior Fellow, Manhattan Institute

QUESTION AND ANSWER SUMMARY

Chairman Ron Wyden (D-OR) – Donald Trump discussed the concepts of a healthcare plan, but the Finance Committee has seen the consequences of his inaction and passed legislation in 2019 to contain costs, including legislation containing the price gouging penalty, but President Trump would not support it. Ms. Aiken, you are paying thousands of dollars a year for your arthritis medication, Enbrel, and have already saved two-thirds of your out-of-pocket (OOP) expenses, correct?

Ms. Aiken – That is correct.

Chairman Wyden – What would happen if most of this law went away?

Ms. Aiken – I "can't even think of where we would be." It would be very difficult.

Chairman Wyden – So you are counting on certainty from Congress to keep building on it rather than unraveling it?

Ms. Aiken – Yes.

Chairman Wyden – JD Vance talked over the weekend about changing risk pools in health insurance. It looks to me like he and Donald Trump want to strip away consumer protections by separating sick and healthy people, which seems like a de facto repeal of protections against discrimination on the basis of pre-existing conditions. What would happen to health insurance if this went into effect?

Dr. Lambrew – Having separate risk pools often leads to higher premiums for people with pre-existing conditions and can price them out of coverage altogether. For a person with cancer, this means they cannot get their chemotherapy; a person with diabetes cannot pay for dialysis. People will experience worse health and could die prematurely. Separate risk pools may seem like a good deal for someone who is young and healthy, but those plans often do not cover the necessary care if there is an accident or unexpected illness. Coupled with not extending the IRA tax credits, this plan would undermine the risk pool, raise premiums, cause more people to become uninsured, cause more uninsured, and effectively repeal the Affordable Care Act (ACA).

Chairman Wyden – I feel strongly about maintaining the tax credits. How much more will families have to pay if the tax credit goes away?

Dr. Lambrew – The Congressional Budget Office (CBO) estimates that 7 million people will lose marketplace coverage, and 4 million people will become uninsured altogether.

Chairman Wyden – 11 million people will be hurt by letting these tax credits expire.

Dr. Lambrew – It's not just families, it is also small business owners and entrepreneurs.

Ranking Member Mike Crapo (R-ID) – It seems like there is price fixing that will result in massive growth in premiums and a federal subsidy to pay for those increases. Mr. Merkel, you and others have expressed concern that the subsidy is inflationary. What approach should Congress follow to avoid the taxpayer subsidizing the fix?

Mr. Merkel – The way the subsidy is structured pegs the value to an insurance plan and caps the contribution that an enrollee must have at their income level. These structures have been found to increase the cost of the underlying product. I recommend looking at the drivers of low quality for the plans, including assessing risk adjustment, which is currently overcompensating for certain populations, refunding CSR payments, and increasing the number of people in the individual market through approaches like the Trump Administration's individual coverage health reimbursement arrangement (HRA).

Ranking Member Crapo – What is the 10-year figure for the subsidy?

Mr. Merkel – It is $415 billion.

Ranking Member Crapo – A recent survey found that because of the IRA's benefit redesign, many Part D plans exclude more medications – including breakthroughs – from coverage and have increased the use of prior authorization and step therapy. Ms. Axelson, you anticipated some of these trends in an article you published this summer. How can Congress and the Centers for Medicare and Medicaid Services (CMS) ensure meaningful formulary oversight, especially considering that drugs were excluded from the Administration's prior authorization rule?

Ms. Axelson – Requiring that a drug be included on the formulary is not enough to guarantee that there won't be hurdles like step therapy. A patient should not have to re-prove that a drug is right for them. Formularies have narrowed over time for a number of therapeutic areas, both in protected classes and non-protected classes, so lawmakers should observe trends over time and ensure the drugs people need are there for them. Just because a drug works well on average does not mean it works well for everyone. CMS has lots of data and can see which therapeutic classes are the ones in which people tend to have to try multiple drugs before they find the right one.

Sen. Maria Cantwell (D-WA) – My constituents are benefiting from the IRA's OOP cap and will benefit from the negotiated rates on drugs. At Costco, buying in bulk gets people a discount; the federal government should be allowed to have the same market power as the private sector. Jardiance is driving a reduction for my constituents – one of my constituents with diabetes has a copay of $500 for a 100-day supply and is considering cutting the dosing, but "if we have something to work out here, they might be able to get that at a cheaper rate." Why is that not good for everyone?

Dr. Conti – To put it simply, it is good for everyone. Seniors win by paying less at the pharmacy counter, adherence will increase and better health will follow, and it is good for pharmaceutical companies to have the prices lower because they will make more sales and generate more revenue.

Sen. Cantwell – Most of the private sector follows this approach because people understand that bulk purchasing leads to selling more product. Pharmacy benefit managers (PBMs) are abusing market power, and Sen. Chuck Grassley (R-IA) and I have tried to take them on over their ability to dictate prices and abuse the market.

Sen. Bill Cassidy (R-LA) – The Biden Administration recently announced a demonstration project for Part D, giving insurance companies $5 billion this year to keep premiums from increasing. On negotiation for drug pricing – as it is currently constructed, PBMs and Part D plans have an incentive to carry the higher priced drug because they get a rebate, so unless we mandate that the lower-priced drug be placed on the preferred tier, are we sure that the beneficiary will be able to access the lower-priced drug?

Dr. Conti – The majority of drugs that will be negotiated in the first and second year are drugs that are largely the ones patients already take every day, and many of them do not have a substitute. My view is that we will not see many restraints on patients accessing these drugs.

Sen. Cassidy – One of the major drugs under negotiation is Humira, which has alternatives. Humira is a "big margin drug." Would that be a high-priced drug that will be negotiated down, but if the new price is not put on a preferred tier, the patient will not see the benefits?

Dr. Conti – My understanding is that people are already gaining access to that therapy and that physicians, PBMs, and insurance companies will not see the benefit in switching patients from Humira to a substitute. Another example of drugs that are already being negotiated are drugs for heart disease; these are drugs for which compliance over time is important for staying well and it is not in the plans' or PBMs' interest to switch patients to a different drug.

Ms. Axelsen – For seven out of 10 drugs, the dominant position on the formulary is third tier access. While price varies widely, the cost is between $45 and $46 for all those drugs. Price is not what determines the copay at the pharmacy for those drugs – after price controls, the price will be about $45. Seniors taking those drugs who retain preferred tier access will retain $45 with or without a price control, but what could be different is the plans may now add prior authorization or step therapy requirements due to losing rebates on those drugs and may go to a competitor to negotiate a discount in exchange for placement without prior authorization or step therapy.

Sen. Cassidy – So Dr. Conti feels like there will be an incentive to maintain, but Dr. Axelsen, you believe that at least for new enrollees, there will be an incentive to switch patients to a different drug?

Ms. Axelsen – Or put up a hurdle "so they can get a discount on a competitor drug."

Dr. Conti – There is no evidence at this point in time that formularies are switching patients away from the products that are being negotiated toward higher-rebated drugs.

Sen. Cassidy – On the separate expiration date for small molecule versus large molecule drugs – there has been a demonstrable decrease in investment for small-molecules, for which the market is primarily Medicare, whereas the drugs that reach the commercial market have continued to see increased investment.

Ms. Axelsen – It is well established that the size of the financial reward is related to investment. Success is unlikely. The lower the likelihood of reward for small molecules, the less investment.

Dr. Conti – There is no empirical evidence to suggest that investment in small molecules is shifting out; if anything, the science is ripe for more development. I agree the IRA shifts incentives for innovation, but there has not been a significant decline.

Mr. Merkel – This is a classic issue with price controls and the incentives they create: there will be resource allocation based on the price controls, and it will not necessarily follow value in the market.

Sen. Chuck Grassley (R-IA) – In 2018, Chairman Wyden and I called for transparency and accountability for PBMs. Four Senate committees, including this one, have advanced PBM legislation, and the Federal Trade Commission (FTC) is also pursuing PBMs. The reconciliation process did nothing to address PBMs. In July, the Administration announced a cost-shifting plan to "hide the negative impact of partisan reconciliation on prescription drug prices" ahead of the November election. Why is the Administration establishing this policy and how much will it cost taxpayers?

Mr. Merkel – The IRA took a previously bipartisan idea – there was support for the OOP cap in Part D – and shifted it in a way that would cost more for taxpayers and possibly for beneficiaries through higher premiums. The Administration saw a premium spike last year and created a Section 402 demonstration project that pays Part D plans around $5 billion to keep premiums lower.

Sen. Grassley – Paragon published a study citing that 5 million people have falsely reported their incomes to qualify for subsidies, costing $20 billion. I sent a letter to the Department of Health and Human Services (HHS) but have not received a response. Is HHS combatting fraudulent activity?

Mr. Merkel – I believe HHS has concerns about fraud, but I do not see willingness to be forthcoming about the magnitude. HHS has announced that it is pursuing roughly 200 brokers, and there is activity where brokers are switching people into plans without their knowledge due to lax program integrity rules, but that is the tip of the iceberg. HHS likely announced that minor action while hoping the rest blows over.

Sen. James Lankford (R-OK) – I appreciate the testimony on Enbrel "because that is one of the frustrating drugs" that "Congress needs to act on" for the patent thicket that prevents generic and biosimilar opportunity and for the PBM piece and huge rebates. The Finance Committee's bill has not been brought to the Senate floor despite being a bipartisan solution to at least some of the PBM issues that will lower prices on not just 10 drugs that the federal government selects but to secure greater competition on thousands of drugs. The solution should be greater competition on all drugs. Ms. Axelsen, what does Congress need to do on PBMs to help pharmacies and to bring down costs and improve access for consumers?

Ms. Axelsen – Many of these reforms are already under consideration, but the main thing is to ensure that discounts offered on these medications are passed through to reduce cost-sharing for patients. Rebates do not always reach patient at the point of sale; they may reduce premiums, but they do not always reduce costs for the patient.

Sen. Lankford – It is frustrating that we have not been able to get the PBM bill to the floor. Drug researchers are concerned about the declining number of drugs entering the research pipeline, especially for drugs that are candidates for multiple uses. I spoke with a researcher who thinks one drug will work with a different kind of a cancer in particular but is "holding on it" because they "don't know what the price controls are going to do" and are "trying to figure out the next step." Reports indicate

there are already 21 drugs that have "backed off" from the market within the past two years. Are we limiting the number of drugs coming to the market? What is happening in clinical trials?

Ms. Axelsen – The most efficient type of clinical drug development is finding new uses for existing drugs because it is cheaper, faster, and relies on existing data. The IRA deters this type of development for a significant portion of drugs for cancer, rare diseases, cardiovascular diseases, and HIV that are studied in the post-market context. This is the worst way to design price controls for Medicare because it encourages inefficient development, and it needs to be reformed.

Sen. Lankford – Congress needs to act on the PBM bill, patent thicketing, active pharmaceutical ingredients (APIs) from China, and generic competition.

Chairman Wyden – I am going to do everything in my power to bring up the PBM legislation during the lame duck session because I believe President Biden will sign it into law.

Sen. Mark Warner (D-VA) – It is hard to find a space with such uniform consensus as PBMs. On drug pricing, I was not always sure if drug pricing was the right angle, but I think we gave the pharmaceutical industry many chances and I do not think it is fair that the U.S. taxpayer subsidizes research and development (R&D) costs for the rest of the world. How will the first round of negotiations move the overall system and benefit Medicare recipients?

Dr. Conti – 9 million Americans will benefit directly from the first round of negotiations and another 5 million will benefit from the second round. The first round of drugs is largely targeted to diabetes and heart disease, so once the prices come down, patients will have more access, and better health will follow. The second round targets specialty classes like cancer and other immunological conditions that have not had the benefit of competition and have limited rebates. Seniors will benefit from lower prices and even commercial insurers will benefit because once the price is set transparently, other plans will likely follow.

Sen. Warner – A real life experience that made me change my point of view is that my daughter has type 1 diabetes and I have seen the cost of insulin rise dramatically. The IRA has brought down insulin costs and I hope the next round of negotiations will continue to demonstrate benefits. No field has shown more promises of technology transformation than healthcare, and all these new technologies will cause costs to go up so we must consider how to recoup some of it.

Sen. George Helmy (D-NJ) – The IRA has allowed states to expand resources and provide better access to care, especially in minority communities. Could you expand on how this improves the physical and economic viability of communities?

Dr. Conti – Lower prescription drug prices benefit seniors, especially low- and middle-income seniors and seniors of color. Adherence to treatment also increases when prices go down, meaning better health, better control of diabetes, and better treatment for cancer will follow.

Dr. Lambrew – Lacking health coverage is one of the major causes of health disparities by race and ethnicity. In the marketplace, there has been tremendous growth in coverage for the Latino, Native American, and other populations that historically lack coverage. Coverage increases the use of preventive care and helps people manage chronic illness better. There is significant impact of insurance coverage.

Sen. Helmy – Access is critical to the innovation economy, especially for small businesses. What is the impact of these subsidies on innovation entrepreneurship?

Dr. Lambrew – The ACA has filled in the gap for people starting businesses and starting out on their own. 50 million people have come into the marketplace to get coverage since the ACA was passed, usually between jobs or starting businesses. My state merged its individual and small group market and is providing reinsurance through the ACA for small businesses. Not extending the policy will harm small businesses.

Sen. Michael Bennet (D-CO) – The U.S. spends more than 17 percent of its gross domestic product (GDP) on healthcare, yet Americans die earlier than residents of peer nations. The IRA took a big step forward with the Medicare price negotiation provision. What is the ripple effect on the overall healthcare system?

Dr. Conti – CBO estimates the law will produce deficit savings. It will also produce savings for individual Americans who have had to choose between paying for their medications and paying for necessities. The system should focus on well care, not sick care; the IRA refocuses on getting people access to the medications they need, which will reduce poor adherence, increase use of products, compress disparities, and spill over into the commercially insured population, thereby increasing access to these therapies.

Sen. Bennet – Could you explain how it will reach the commercial market?

Dr. Conti – With more transparent prices, commercial plans will demand similar price declines, especially for drugs for which there is little competition and for which plans have previously been unable to negotiate lower prices.

Sen. Bennet – As the number of drugs under negotiation increases, will that have a ripple effect on prevention and other aspects of how the U.S. healthcare system seems to have poorer outcomes than other countries' systems?

Dr. Conti – Yes. Bending the cost curve in the U.S. will require addressing prices. The IRA tries to lower prices for taxpayers and for Americans at the pharmacy counter, leading to better chronic disease management and more uptake of preventive products like vaccines.

Sen. Bennet – I do not understand how people voted against capping the price of insulin, having Medicare negotiate the price of drugs, or other provisions in this bill.

Sen. Todd Young (R-IN) – Democrats said the IRA would lower costs, but premiums have risen and plan choices have decreased. Seniors will have higher copays for drugs selected for negotiation. Ms. Axelsen, what will be the impact on access and OOP costs for the drugs selected for the first round of negotiation?

Ms. Axelsen – For seven of the 10 drugs, their dominant position on the formulary is already third tier or better with a $45 or $46 copay. The seniors who are already on these drugs or who are receiving the Low-Income Subsidy (LIS) will not see an effect. For people taking a specialty drug, there is a $2,000 OOP cap regardless of whether the drug has a price control. Some of the savings are accrued to the federal government and some of it is disappearing because premiums are going up.

Sen. Young – Who benefits from the price setting provisions?

Ms. Axelsen – There are some savings to the federal government and some satisfaction is gained by people who feel the government should be setting prices. This is not a negotiation; people can walk away from negotiations.

Sen. Young – What will be the long-term impacts on seniors' access to these drugs and drugs selected for future rounds of negotiation?

Ms. Axelsen – Given that this erodes the potential of launching generics, there is the possibility that seniors will not see the benefits of generic and biosimilar entry into the market. Big markets attract competition, which lowers prices. Price controls deter this type of activity.

Sen. Young – The Finance Committee is concerned on a bipartisan basis about drug shortages. Many manufacturers are ceasing to produce low-cost drugs because reimbursement is too low. The IRA penalizes manufacturers who seek to increase prices on drugs, which will exacerbate shortages. Should special consideration be provided to drugs in shortage to exempt them from price inflation penalties and include other categories of medicines prone to shortages, like generic sterile injectables, to ensure they are still produced?

Ms. Axelsen – The price controls will create shortages. In Medicaid, even when other suppliers are entering the market, manufacturers cannot increase costs without incurring that penalty even if they enter the market at a lower price than other suppliers.

Chairman Wyden – Ms. Aiken is spending thousands of dollars for her arthritis medicine and testified that she is saving thousands of dollars in OOP costs.

Sen. Elizabeth Warren (D-MA) – Democrats passed the IRA without a single vote from Republicans. Seniors are already feeling relief: one of my constituents used to pay $150 a month for her insulin but now pays only $35, others are saving an average of $3,700 a year on premiums for ACA coverage, and another half a million will save an average of $330 million prescription drugs by next year. These savings "are completely paid for by my 15 percent corporate tax on billionaire corporations." Eight of the largest drug companies have sued the federal government to block Medicare negotiation. The industry claims negotiation will harm pharmaceutical innovation. Dr. Conti, does research support this?

Dr. Conti – No. Stock prices for the affected companies are going up, merger and acquisition (M&A) activity is rising, and R&D spending is up.

Sen. Warren – So what is happening is the exact opposite of what is happening in court. Last year, Bristol Myers Squibb made more than $12 billion "on its blockbuster blood thinner," Eliquis, which is one of the first 10 drugs selected for negotiation. Its price will be cut in half for nearly 4 million seniors. The company's CEO recently told investors that he was "confident in the company's ability to navigate the impact of the IRA on Eliquis." Is BMS's view unusual compared to other drug companies?

Dr. Conti – No, it is in line with what other companies are telling their shareholders and Wall Street. They are saying the IRA is inducing them to look for opportunities for growth, take more risks, and put more money toward bringing new products to market.

Sen. Warren – These companies are going to court "and play the violins" but are telling their investors they are investing more than before.

Dr. Conti – They are also giving stock buybacks and dividend payments to shareholders.

Sen. Warren – Drug companies want Americans to believe that "charging fair prices for drugs will jeopardize innovation." These same companies have underinvested in R&D for years. Democrats called the industry's bluff, and the work is not finished – it is time to expand the IRA's protections.

Chairman Wyden – Sen. Sherrod Brown (D-OH) has led the Finance's Committee's efforts on stock buybacks and I proudly support his work.

Sen. Sheldon Whitehouse (D-RI) – A clinic in Rhode Island used to run a vaccine program that is now overwhelmed with seniors due to the IRA's vaccine cost-sharing provision. Do vaccines reduce healthcare costs from preventive diseases?

Dr. Conti – Yes. 6 million seniors have received an RSV vaccine in the past year and millions of seniors have also received a shingles vaccine. Prevention works.

Sen. Whitehouse – CBO has predicted that negotiation will save $25 billion in 2031 with cumulative savings of $100 billion over 10 years. Does that sound correct?

Dr. Conti – Yes.

Sen. Whitehouse – The IRA extended expanded tax credits which are set to expire in 2025. Will there be a good outcome if Congress fails to extend them?

Dr. Lambrew – No. 10 million people will lose marketplace coverage and 4 million will become uninsured. Younger people will drop out, costs will become higher, and it will harm older people. This is important.

Sen. Whitehouse – Rhode Island had two of the best performing Accountable Care Organizations (ACOs) in the country early on. I believe transitioning away from fee-for-service (FFS) toward value-based payment systems creates enormous saving opportunities. In Rhode Island, one individual was provided an air conditioner and a television and his emergency room (ER) usage declined significantly thereafter. Would the transition from FFS to value-based care provide healthcare savings, and how can Congress apply lessons learned from ACOs, which are happier patients, better outcomes, and lower costs? Please respond for the record.

Sen. John Barrasso (R-WY) – The IRA prioritized electric vehicles over patients, especially those living with rare diseases. Prior to this law, Congress spent decades building support for orphan drug discovery and development, including ALS, rare cancers, and sickle cell disease. Policymakers incentivized innovation, resulting in hundreds of rare disease drug approvals, many treating up to eight conditions. This reckless law has replaced optimism with uncertainty for patients and manufacturers. While the law claims to protect rare disease drugs from its price setting programs, it only protects drugs approved for a single rare disease. Drugs approved for multiple rare diseases are "on the chopping block," and this disincentive is already impacting innovation: multiple clinical trials looking for additional rare disease indications have been withdrawn as a result of the law. Drug companies consider launching rare disease drugs abroad instead of doing it in the U.S. first because of this short-sighted policy. How will this limitation impact people in rare disease communities?

Ms. Axelsen – Around 35 percent of rare disease drugs have historically been approved for more than one indication, so simply exempting the drugs that only have one indication is not a protection for rare disease treatments. The most efficient way to develop a drug is to develop a mechanism for a particular disease; once finding that it works on a certain part of the body, researchers can find that it works on that part of the body for another disease. That is how rare disease medicines can be a profitable endeavor. These therapies also tend to have high price tags, and I appreciate that there is concern about cost and affordability, but the law does not root out inefficient spending – instead, it roots out the drugs that are often popular, well needed, and have demonstrated benefit to patients. Exempting the drugs that have one single orphan indication is not enough to protect people with rare diseases.

Sen. Barrasso – I imagine this harms people around the world as well.

Ms. Axelsen – The U.S. is the North Star for drug development, making up 40 percent of all revenues and more than 50 percent for orphan and rare diseases. Big companies will survive this by shifting their investments away from things like rare diseases, particularly those that affect seniors and disabled people. A small biotechnology company that has a drug in development for a rare condition in a senior population will not be able to sustain investment.

Sen. Barrasso – In July, the Biden-Harris Administration announced a nationwide voluntary Part D premium stabilization demonstration as part of its Medicare drug benefit redesign claiming that it is lowering the cost of premiums for seniors, but in reality, the redesign is hiding failure. The Wall Street Journal published an editorial in August titled "Biden Does a Stealth Medicare Rewrite." This is a $5 billion program that pays insurers to stabilize premiums instead of being honest about failures. People in Wyoming are wondering why taxpayers are paying insurers to keep premiums low.

Mr. Merkel – The IRA took a previously bipartisan idea to cap OOP costs for seniors and modified it to push to costs onto taxpayers in a way that spiked beneficiaries' premiums. The law included a provision to keep the premiums artificially low, but the $40 billion cost of the provision was not enough to prevent a spike. The demonstration project is not really a demonstration project, it is just paying insurance companies to keep the premiums low without solving the underlying problem.

Sen. Catherine Cortez Masto (D-NV) – The IRA is helping people in Nevada access vaccines for free, capping insulin prices, lowering ACA health premiums, and helping low-income people afford their medications. More than 65,000 Nevadans will benefit from upcoming price negotiations. Ms. Aiken, you have benefitted from the IRA, correct, and Mr. Merkel, you would not want to take that benefit away from her, would you?

Ms. Aiken – Absolutely.

Mr. Merkel – No.

Sen. Cortez Masto – There are always opportunities to improve legislation. What are the challenges within the IRA and is there ability to improve upon it, or is there more information and data needed first?

Dr. Conti – There is evidence that there will be spillovers of direct patient benefit, lower costs, and more expanded use into the commercial insurance sector, but if we want to ensure that commercially insured working men, women, and children get access to the drugs they need, we should consider guaranteeing those benefits in the commercial market. On innovation incentives, there is no evidence of clinical programs sunsetting because of the IRA; if anything, the industry is looking for opportunities to bring new medicines to market because it is facing a generic patent cliff in the next five years. The IRA shifts incentives for companies to conduct parallel trials across many indications to bring all products for all indications more swiftly to gain as much revenue as possible, and this will benefit Americans who will not have to wait as long for more indications.

Dr. Lambrew – There is an important difference in the IRA between the drug parts of it and the health coverage parts of it. In six months, all the insurance commissioners will be looking to see what to do; nine months from now, insurance companies may decide to raise their premiums because the tax credits end in 15 months. I know there has been discussion of fraud, and I know Chairman Wyden has a bill to tackle agents and brokers who are fraudulently signing middle-income people up. Fraud should be addressed, but getting rid of these tax credits is a step in the wrong direction.

Sen. Cortez Masto – Everyone in this country should have access to affordable healthcare when they need it, and they should not be priced out of it. Our goal as policymakers should be to achieve that outcome, not to put more money in PBMs' or the pharmaceutical industry's pockets.

Sen. Steve Daines (R-MT) – The IRA's negligence and haste has resulted in reduced investment in R&D for cutting-edge drugs that would save lives. The companies with drugs selected for the first round of negotiation have communicated that the IRA will limit the ability to discover and develop new and innovative medicines, and ultimately, the average American will suffer the most. The Administration also just announced a new demonstration program to hide the catastrophic effects of premium increases so Democrats can "escape the optics" of higher premiums in an election year. Democrats intend to make permanent the IRA's enhanced premium tax credits; CBO estimates this will cost $415 billion. Mr. Merkel, can you elaborate on your testimony that this tax credit does not lower the cost of insurance or improve the value of ACA plans?

Mr. Merkel – People stopped purchasing ACA plans with their own money without a government subsidy "quite some time ago" because premiums and cost sharing are higher and networks are narrower. The IRA covers these concerns with more money for insurance companies, but it does nothing to resolve the underlying problems. In some states, roughly half of people now pay nothing for a plan, meaning the insurance company is no longer designing the plan to be of value to the person who is buying it; rather, the plan is designed to comply with government regulations. I anticipate that plan quality will decline.

Sen. Marsha Blackburn (R-TN) – Seniors have seen their choices diminish and their premiums increase. Mr. Merkel, the taxpayer costs associated with Part D premium stabilization efforts and with the PTC expansion – how do you see these policies affecting the long-term affordability and access for seniors?

Mr. Merkel – These are both part of a disturbing trend. For the ACA, it is narrowing networks, high cost sharing, and high premiums, and for Part D it is a premium spike and dwindling plan choice. The immediate response is to throw more taxpayer money at it, which is not a long-term solution and is expensive.

Sen. Blackburn – The IRA's price controls are problematic. 21 drugs and 36 research programs have been halted due to the IRA, and forecasts suggest that 188 fewer small molecule treatments will be brought forward over the next 20 years. What actions can Congress take to ensure innovation continues?

Ms. Axelsen – If we feel that price controls are necessary, they should not be implemented until at least 13 years after the drug is approved. This differentiation between small and large molecules has no evidence and it discourages the most efficient type of drug development.

Sen. Blackburn – What about biosimilars?

Ms. Axelsen – The government is discouraging the launch of biosimilars and generics by pushing the price of a drug down toward the end of the life cycle with a price control.

Sen. Blackburn – The Finance Committee is looking at this and has already advanced some PBM reforms; we know these changes would increase biosimilar uptake and would lower costs for patients. Small molecule drugs are vital for treating diseases like Alzheimer's and some cancers. The IRA's accelerated price setting would hamper access to that market.

Sen. Tom Carper (D-DE) – The IRA made landmark achievements on vaccines, insulin, OOP costs, and Medicare drug price negotiation, which is an authority that the Department of Veterans Affairs (VA) has had for a long time. Delaware residents are already experiencing lower costs for their prescription drugs and insulin. Delaware has a rising aging population, underscoring the need for affordable healthcare for Medicare beneficiaries. How would it impact seniors if the IRA were repealed or rolled back?

Dr. Conti – Seniors have already benefitted from OOP caps on drugs like insulin and adult vaccines. 9 million seniors will benefit directly from price negotiation on prescription drugs that they use every day to manage their diabetes and heart disease. In addition, another 5 million will benefit from the next round of negotiation; these seniors have cancer and other immunological disorders. Repealing the IRA will take money out of their pockets and reduce their adherence to treatment.

Sen. Carper – Ms. Aiken, I would like you to answer the same question for the record. You noted in your testimony that as a nurse, you spent years advising patients on the importance of adhering to medications. What was your experience with patients who struggled to afford their prescriptions and what sacrifices did they have to make?

Ms. Aiken – We frequently heard from patients who had not taken their prescribed medication for two weeks because they could not afford it. In my own case, if my financial obligations were higher than usual, I might skip a dose of my Enbrel to delay paying that several hundred dollars so I could take care of my other bills that month.

Chairman Wyden – This testimony "made me wonder about getting commonsense Medicare cost containment back in fashion." Sen. Grassley and I previously had a bipartisan proposal on price gouging; it was not exactly the way Sen. Grassley would have written it, but he implored President Trump to support it. We can build on these good ideas because when the government does something, the private sector can follow. This is a wakeup call about not turning back the clock. JD Vance's suggestion on splitting up risk pools would go back to discriminating against people with pre-existing conditions. Ms. Aiken testified that she was spending thousands of dollars a year on her arthritis medication before the IRA. We need to keep it in place and build on it. I am also going to do everything I can "to get PBM cost containment on medicine" brought up in the lame duck session.

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*Please click **here** for the archived hearing.*