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Mandates, Meddling, and Mismanagement:
The Inflation Reduction Act's Threat to Energy and Medicine

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Key Points:

1) Biomedical innovation is an American success story, but the drug pricing provisions as implemented under the Inflation Reduction Act (IRA) threaten continued therapeutic advances. The evidence is clear that reducing expected revenues, for example, through drug price "negotiation," reduces the number of new drugs entering the market and is likely to shorten life expectancy.

2) The IRA includes particularly concerning provisions that undermine progress in treating rare disease and disincentivize investment in small molecule drugs.

3) The implementation of the IRA's inflation rebate provisions encourages higher launch prices, discourages studies of real-world efficacy, hinders negotiations with private payers, and generally decouples drug prices from real-world value.

4) Part D benefit redesign was needed to restore competition in the market, and patients benefit from the insurance protection provided by the new out-of-pocket cap. But early implementation has distorted the market and increased taxpayer subsidies from approximately 75% of base spending historically to 83% in 2025.

Chairmen Burlison and Grothman, Ranking Members Frost and Krishnamoorthi, and distinguished members of the Subcommittees, thank you for the opportunity to testify about how the implementation of the Inflation Reduction Act (IRA) is a threat to medicine.

My name is Erin Trish and I co-direct the Leonard D. Schaeffer Center for Health Policy & Economics at the University of Southern California. Since its founding in 2009, the Schaeffer Center has established itself as one of the nation's leading health economics organizations. At Schaeffer, we strive to measurably improve value in health through evidence-based policy solutions, research excellence, and public and private-sector engagement. As part of this mission, my colleagues and I have been studying prescription drug markets for decades. The opinions I offer today are my own and do not represent those of the University or the Center.

Biomedical innovation is an American success story. Over the last 50 years, we've seen incredible progress in our ability to treat cancers, cardiovascular disease, obesity, hepatitis, HIV, and other complex conditions. American patients routinely get earlier access to these breakthrough treatments, improving outcomes. Indeed, Schaeffer research has shown that cancer patients live longer in the US than Europe, and the additional spending associated with better survival is well worth the extra cost in health and economic returns.

However, biomedical innovation is an inherently risky and costly undertaking. Most drugs fail in clinical development, and even more research projects never make it that far. Thus, to undertake the risk of continued biomedical discovery, innovators and investors must expect positive returns and a transparent, predictable market.

Unfortunately, the IRA's prescription drug-related provisions have the potential to upend this progress.

The IRA's drug-pricing provisions generally include three key features:

1) Requiring the government (via the Centers for Medicare and Medicaid Services (CMS)) to determine prices for certain single-source drugs covered under Medicare Part B and Part D;

2) Requiring manufactures to pay rebates to Medicare if a drug's list price in Part B or Part D increases faster than the consumer price index; and

3) Reforming the Medicare Part D benefit design, increasing liability among Part D plans and required manufacturer discounts, while capping beneficiary out-of-pocket spending.

Taken together, these provisions pose a significant threat to biomedical innovation. Moreover, while benefit modernization was needed in Part D, early evidence indicates the early implementation of the IRA has distorted the market, increased federal subsidies, and likely increased out-of-pocket costs for many beneficiaries.

Drug Price "Negotiation" Hurts Patients

Policy interventions that change the expected future revenues of innovative firms—like those included in the IRA—affect firms' anticipated and current profits. Firms, in turn, respond by adjusting their investment in research and development, the key engine to innovation. And future biomedical innovation—from new breakthrough treatments to improved formulas and reduced side effects—directly impacts our future health.

Schaeffer research finds that a 10% reduction in expected U.S. pharmaceutical revenues would lead to a 2.5% to 15% decline in pharmaceutical innovation. The evidence is clear that by reducing pharmaceutical revenue, the IRA will result in fewer drugs coming to market. Ongoing Schaeffer research indicates that the drugs we lose are not simply me-too products, but rather high-quality, clinically-meaningful new treatments. Indeed, some have estimated that widespread drug price negotiation could reduce life expectancy by 2 years for 35-year olds as innovation falls.

IRA Undermines the Fight Against Orphan Diseases

The IRA's impact on orphan drug development warrants particular attention. For patients with a rare disease, treatment options are often limited, despite landmark progress due to the 1983 Orphan Drug Act. We only have FDA-approved treatments for 500 of the roughly 7,000 rare diseases with a known molecular mechanism. Schaeffer research has also shown that society highly values treatments for rare and complex diseases. Rare disease patients are willing to pay higher prices for these treatments and patients with terminal illnesses value medical innovation more than those who are in good health.

While orphan drugs that treat a single, rare disease are exempted from the Medicare Drug Price Negotiation program, drugs that are approved for additional indications lose their exemption status. This potential loss of incremental innovation will have meaningful impacts on patients. Research shows that 63 of the 280 orphan drugs developed between 2003 and 2022 secured at least one follow-on indication—a pathway that increases treatment options for patients with rare diseases and provides manufacturers an opportunity to expand their original market.

Moreover, the implementation of the IRA perversely disincentivizes innovators from bringing orphan drugs to market quickly if they expect approvals for subsequent indications because the clock starts ticking toward negotiation eligibility with a drug's first indication. To make this concrete, consider an innovator with an investigational drug to treat a high-need, orphan condition. However, this drug may also have therapeutic uses for another condition with a much larger treatment population. The innovator will think twice about bringing the drug to market for the orphan indication under an accelerated approval process, because doing so would start the clock toward negotiation before launching for the broader patient population, sometimes by years. In this way, patient access to novel therapies for serious, life-threatening diseases will be delayed. Policies like the ORPHAN Cures Act could help address some of these concerns.

IRA Discourages the Development of Small Molecule Drugs
The IRA also reduces the incentives to develop small molecule drugs by reducing the number of years of exclusivity compared to biologics. Specifically, small molecule drugs can be eligible for Medicare Drug Price Negotiation nine years after FDA approval, while large molecule drugs have thirteen years of market exclusivity before they become eligible.

Schaeffer research shows that disadvantaging small molecule drugs is a mistake. Small molecules represent some of the most promising scientific breakthroughs. Unless we level the playing field, we'll likely see researchers turn away from small molecule treatments that target proteins long considered "undruggable" and offer our best hope to find cures for cancer, Alzheimer's, Parkinson's and more. Policies like the EPIC Act could help to address the disincentives created by this "pill penalty."

Initial Negotiation Process was Opaque and Did Not Achieve Meaningful Savings
In August 2024, CMS published the Maximum Fair Prices (MFPs) it had determined for the ten products selected for the first round of Medicare Drug Price Negotiation, with those prices set to take effect in 2026. CMS stated it "negotiated in good faith" and "engaged in genuine, thoughtful negotiations." However, there is little transparency into how CMS weighed different factors and ultimately determined those prices. CMS' explanations for its processes provided limited insight into how it valued health benefits and how it translated clinical benefits into value. Recognizing this opacity, just last week CMS released draft guidance for the third cycle of the Medicare Drug Price Negotiation program, including policies intended to promote greater transparency and reduce administrative burden.

Despite a convoluted process, CMS arrived at prices strikingly similar to the net prices achieved through negotiations between Part D plans and drug manufacturers. While CMS published eye-popping discounts ranging from 38-79%, those discounts are relative to the drugs' list prices. Researchers estimated much more modest discounts relative to net prices, ranging from 0-27%.

CMS did acknowledge the existence of these significant existing discounts on these drugs, estimating that, in aggregate, if the MFPs "had been in effect during 2023, the negotiated prices would have saved an estimated $6 billion in net covered prescription drugs costs, which would have represented 22% lower net spending in aggregate." But even this estimated is inaccurate, as it did not account for additional subsidies CMS must provide for these drugs starting in 2026 in lieu of manufacturer discounts required under Part D redesign. Moreover, it did not account for the fact that the lost rebates on these products is expected to increase overall federal spending on Part D in 2026, as projected by economists from CMS' Office of the Actuary.

While the magnitude of potential savings in future years is not yet known, the first year of the process introduced considerable complexity and opacity while achieving limited to no meaningful savings, notwithstanding the prior Administration's claims.

Inflation Rebates Encourage Higher Launch Prices and Hinder Payers
The IRA's inflation rebate provision—requiring manufacturers to pay a rebate to CMS if their list prices increase faster than inflation—might make sense if we knew the true value of a drug upon its launch, and its long-term, real-world benefits were known with certainty. Rarely, if ever, is this case. Indeed, launch may be the worst time to lock-in prices.

More commonly, a drug's estimated value emerges over time as additional data are collected. Only after FDA approval will data emerge through confirmatory trials (e.g., those that assess overall survival) or observatory real-world data studies (i.e., those that estimate treatment effectiveness in the real world). For example, as a drug enters the market, patients and physicians gain experience using the treatment while real-world effectiveness and safety data are collected.

The IRA's inflation rebate hampers efforts to tie value of a drug to increased evidence of effectiveness. Instead, the IRA encourages manufacturers to launch at the highest price possible—since it will be capped going forward. It also disincentivizes the conduct of confirmatory trials to estimate real world efficacy, since manufacturers whose drugs show the greatest long-term value are penalized for raising prices above inflation.

Payers also miss out on information that would help them in their private negotiations with manufacturers. New evidence might show lower value than expected; this would help payers negotiate more favorable prices. Furthermore, because of the inflation rebate provision, manufacturers are less willing to reduce prices immediately in the hope that favorable long-term evidence will emerge.

A Better Approach: Three Part Pricing to Expand Access and Link Prices to Value
Schaeffer colleagues have written about a better approach to pricing known as three-part pricing. With this strategy, drugs first undergo an initial "evaluation phase" in which manufacturers launch their drug with a low price with the incentive to generate new evidence around treatment efficacy, effectiveness, and safety over a period of time. In the UK, for instance, NICE may approve a treatment for a more restricted set of conditions until additional, more robust evidence is generated. However, using a low launch price would improve uptake and access to the drug by patients in the short term, and would also accelerate the rate of real-world evidence regarding the drug's effectiveness. During a subsequent "reward phase," the drug's price would reflect the degree to which new evidence has or has not demonstrated changes to the initial estimates of treatment safety and effectiveness. Finally, the "access phase" would utilize robust generic and biosimilar competition to discount branded prices upon its loss of exclusivity, accomplishing the IRA's intended goal of lower drug prices and improved patient access in the long term.

Part D Standard Benefit Needed Modernization

The original Medicare Part D standard benefit design (which took effect in 2006) included several provisions—such as federal reinsurance for enrollees with high drug costs—intended to encourage private plans to participate in the market. This made sense in the early years of Part D but, as prescription drug markets evolved, plans did not have enough skin in the game to maintain robust competition. My colleagues and I showed that, as of 2016, Part D plans were only liable for about one-third of total Part D spending, with the federal government directly paying the majority of costs. Additionally, the lack of an out-of-pocket cap meant beneficiaries did not have true insurance protection.

The need for reform to restore competition and protect beneficiaries from catastrophic costs was well recognized. Indeed, prior to the passage of the IRA, bipartisan proposals were under discussion that aimed to achieve these goals. The implementation of the IRA's major benefit redesign provisions—which took effect this year—protect beneficiaries from high out-of-pocket costs and shift much more responsibility to plans and manufacturers. But their abruptness and significance has created market instability and considerably increased federal spending.

IRA Redesign Shrunk the Number of Stand-Alone Part D Plans

In 2025, there are a total of 464 stand-alone Part D plans (PDPs) offered in different markets around the country, down 35% from 2024. This is the fewest plans ever offered in the program's twenty-year history. In 2025, a typical beneficiary can choose from about 12-16 PDPs, compared with about 21 last year. Indeed, one recent study found that 7.5% of Part D beneficiaries (including those in both PDPs and Part D plans integrated with Medicare Advantage (MA-PDs)) lost their insurer from 2024 to 2025, compared with 0.1% to 2.3% losing their insurers in a given year from 2018 to 2023.

IRA Substantially Increased Federal Premium Subsidies

Part D plans (including both PDPs and MA-PDs) submit bids to CMS reflecting the total revenue they must collect—between beneficiary premiums and various federal subsidies—to operate in the market. While the details of how Part D premiums and subsidies are calculated gets complicated quickly, at a high level, federal taxpayers have historically subsidized about 75% of these bids, with beneficiaries paying about 25% in premiums.

However, the IRA includes a provision capping base beneficiary premium growth—or the national average beneficiary premium for a plan equivalent to the standard benefit design—at no more than 6% annually from 2024 through 2029. Historically, base beneficiary premiums have been quite stable, averaging between $27-36 dollars per member per month from 2006 through 2023. However, with the implementation of the IRA's benefit redesign, the base beneficiary premium would have increased considerably—to $56 per member per month in 2025. The IRA's 6% cap on premium growth held the actual base beneficiary premium to $37, but this required an additional federal premium subsidy of $19 per member per month. As a result, in 2025, taxpayers are subsidizing 83% of base Part D program spending rather than the historical 75%.

Premium Stabilization Demonstration Further Increased Federal Subsidies
Subsequent to receiving bids for the 2025 plan year, CMS announced a PDP premium stabilization demonstration. The demonstration applies only to PDPs and 1) reduces base beneficiary premiums by an additional $15 per member per month; 2) limits a plan's total premium increase to no more than $35 per member per month; and, 3) adjusts the Part D risk corridors program to provide for greater government sharing for potential plan losses. The demonstration may continue for up to two additional years.

The Congressional Budget Office estimated the premium stabilization demonstration would cost approximately $5 billion in 2025 alone, above and beyond the additional taxpayer subsidies described above. However, these additional subsidies also introduced significant premium distortions into the PDP market. In ongoing analyses, my colleagues and I are finding that, thanks to these additional subsidies, approximately one-quarter of PDP beneficiaries actually pay no ($0) premium in 2025. This is unprecedented, and reflects the variability in plan bids and the fact that these additional subsidies were made available to all PDP enrollees, regardless of the cost of their actual plan. Even more perplexing, we are finding that most $0 premium plans are enhanced plans—meaning they are more generous than the standard Part D benefit and should have otherwise been expected to have *higher* premiums. The way these additional subsidies were applied allowed enhanced plans to take even greater advantage of them.

Plans Have Changed Their Benefit Structure in Response to Redesign, Likely Increasing Out-of-Pocket Costs for Many Beneficiaries
While the IRA's out-of-pocket cap provides much needed insurance protection for beneficiaries, other changes have likely increased out-of-pocket spending for the majority of beneficiaries who do not reach the cap (totaling $2,000 in 2025). In forthcoming Schaeffer research, my colleagues and I find notable changes in plan design exposing many beneficiaries to higher out-of-pocket costs in 2025, especially among MA-PDs. For instance, the average annual deductible among MA-PD enrollees increased from $60 in 2024 to $224 in 2025. Among PDP enrollees, the average annual deductible increased from $425 to $491. We also find that the proportion of MA-PD enrollment in plans using coinsurance (rather that copayments) for preferred brand drugs increased from 4% in 2024 to 29% in 2025. In previous research, we showed that this switch to coinsurance—which increases beneficiaries' out-of-pocket costs relative to copayments—has been occurring among PDPs for several years, but the 2025 change among MA-PDs is striking.

These shifts in plan design reflect IRA Part D rules that make it very costly for plans to offer reduced deductibles or flat dollar copayments for branded drugs. What it means is that, while all beneficiaries now have the added protection having their out-of-pocket expenses capped at no more than $2,000 in 2025, many beneficiaries—who will not reach that cap—are likely facing higher costs for their prescription fills than they did in previous years due to higher deductibles and higher out-of-pocket payments as their plans switch from copayments to coinsurance.

Thank you for the opportunity to be here. I look forward to your questions.