COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

**Testimony of Joel C. White**
**President, Council for Affordable Health Coverage**

**To the Subcommittee on Health Care and Financial Services**
**Committee on Oversight and Accountability**

**On "The Inflation Reduction Act: A Year in Review"**

*September 14, 2023*

## Introduction

Chairman McClain and Ranking Member Porter, I appreciate the opportunity to testify today regarding the Inflation Reduction Act (IRA). My name is Joel White, and I am the President of the Council for Affordable Health Coverage. CAHC is a broad-based alliance with a singular focus: bringing down the cost of health care so that all Americans have access to affordable coverage. Our membership reflects a broad range of interests, including organizations representing small and large employers, patient groups, consumers, and insurers.

We all want lower health costs. As costs rise, our premiums and out-of-pockets costs increase, which reduces access to care and take home pay. Taxpayers also pay more when costs increase in government run programs. Reducing health spending is therefore critical to improving our health outcomes, our standard of living, our economic prospects, and our security as a nation.

The IRA is sprawling effort to raise taxes, expand government subsidies for private companies in the energy space and for Obamacare, and hire new IRS employees, among other changes. It also dramatically expands political and bureaucratic involvement in our health care, primarily with respect to prescription drugs and Medicare. In my opinion, it will increase long term health costs.

My testimony regarding the IRA after one year focuses on the health aspects of the law, and makes the following points:

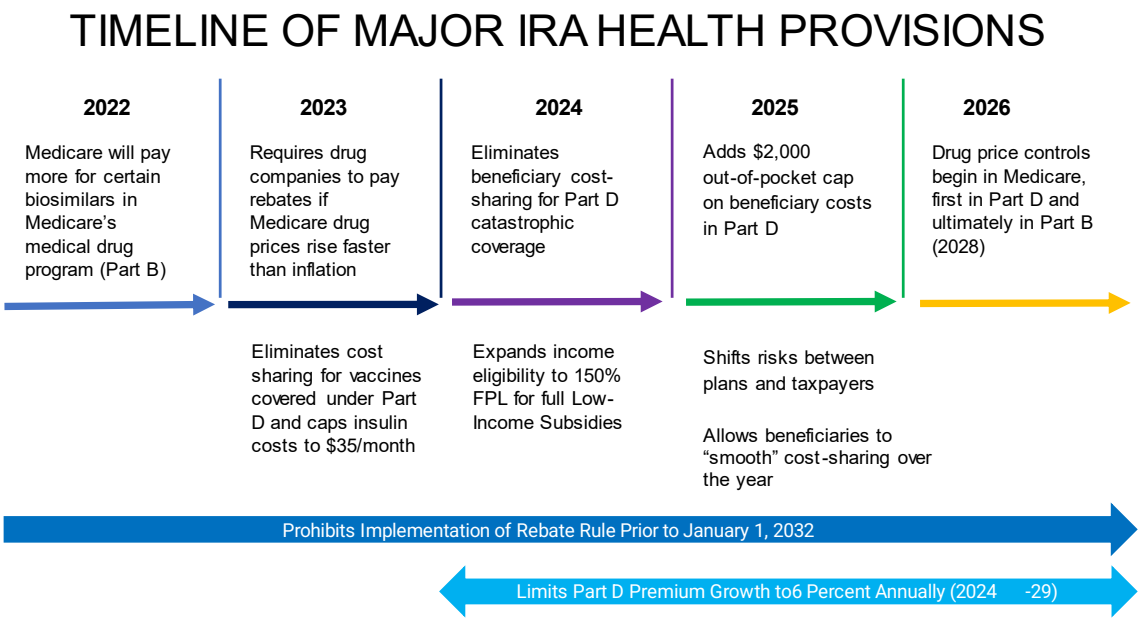
1. The law empowers politicians and bureaucrats to make decisions impacting the public's health coverage in secret, bypassing public notice and comment process and judicial oversight. This Committee must aggressively conduct oversight to hold decisionmakers accountable;

2. The law and its implementation have profound negative implications on health care, including access to care for vulnerable populations, costs, and the future availability of innovative treatments; and

3. Congress should amend the law to improve access and lower costs without harming innovation. Congress must also act to re-establish transparency and accountability so that all Americans have insight and input into how the IRA is implemented.

## Background

The health provisions of the IRA are a massive undertaking involving the creation of a new bureaucracy, hiring of new staff, new taxes on drugs, and conducting a back-and-forth price setting exercise for drugs made by private companies (depicted in the chart below). A law of this magnitude and complexity should have robust stakeholder feedback, including diverse views from every party impacted, as laid out in the normal rulemaking process that has been in place for almost 80 years. Congress, however, exempted the IRA's programs from the normal process. As a result, politicians and government bureaucrats are implementing the law without adequate transparency or accountability.




This Congress should ensure that the law is opened up to sunlight so that patients and taxpayers know how decisions about their health benefits are being made, when and by who.

## The Medicare Part D Benefit – A History

As professional staff on the Ways and Means Committee, I was a member of the small group who helped Congress design and draft the bipartisan Medicare Modernization Act of 2003[1], which created the Medicare prescription drug (Part D) benefit. After the law was enacted, I became Staff Director for the Ways and Means Health Subcommittee and worked collaboratively with the Bush Administration to implement the MMA to ensure maximum benefits for patients and taxpayers.

In crafting the law, we sought to balance limited taxpayer funds with a robust benefit. The intent was for aggressive Part D plan competition and negotiation to drive substantial savings for beneficiaries. Congress included a provision known as the "non-interference clause" that prohibited the HHS Secretary from interfering in the private price negotiations between Medicare Part D plans, drug manufacturers, and pharmacies. Instead, Part D plans negotiated substantial discounts and rebates with drug manufacturers that allowed plans to offer low premiums to their customers.

The law includes flexibility in benefit design (reduced cost sharing like zero-dollar deductible plans) and premium competition (like zero premium offerings). We also took great care to write into the law pro-patient standards for access to pharmacies, minimum access to drugs by therapeutic class, requirements to expedite appeals and plan disputes, and mandates to include physicians and pharmacists on pharmacy and therapeutic, clinical review committees. We wanted this program to be run by benefit design experts and doctors and other health professionals to benefit patients. The goal was a competitive market, subsidized by taxpayers, with incentives to compete for customers on superior quality and price.

[1] E:\PUBLAW\PUBL173.108 (congress.gov)

And it worked. Part D is and has been one of the most popular and successful health programs ever designed, with regular consumer satisfaction surveys near or above 90 percent, robust choice of affordable plans, and taxpayer costs well below CBO projections.

## Congress Creates the IRA

In 2022 Congress decided to create the Medicare Drug Price Negotiation Program, which moves away from a competitive, plan-manufacturer negotiating structure in Part D to a price setting program run by politicians and government bureaucrats.

More specifically, the IRA repeals the "non-interference clause" and allows the government to interfere in drug markets by imposing price controls in Medicare's retail drug benefit (Part D) and medical drug benefits (Part B). The Department of Health and Human Service assesses the top gross spending drugs in Medicare for potential selection in the program. HHS will select 10 negotiation-eligible drugs in 2026, 15 in 2027 and 2028, and 20 drugs every year thereafter. The list is cumulative; ultimately most drugs in Medicare will be on the price control list. Once selected, drugs continue to remain on the list unless there is a generic competitor.

For negotiation-eligible drugs, the HHS Secretary makes an offer, the manufacturer can make a counteroffer, but in the end, there are maximum price caps, but no floor on the HHS offer price – meaning the Department could offer to pay as little as $0.01 for the drug.

It is also important to recognize this is ***not*** negotiation as understood by most Americans – it is an unlevel playing filed where Congress granted the administration authority to impose excessive fines and unusual penalties for drug manufacturer non-participation. If a manufacturer refuses the offer from HHS, they are subject to a tax equaling as much as 95% of product sales. The law defines the tax rate as the ratio of the tax to the price net of the tax, resulting in an effective tax rate that would start at 186% of total sales and increase up to 1,900% of total sales.[2] This is excessive as companies would pay more in tax than revenue generated by sales. It is also unusual

[2] The excise tax begins at 65% for the first 90 days of noncompliance, increases to 75% from days 91 to 180, is 85% for days 181 to 270, and increases to 95% in subsequent days of noncompliance. Because of the way the law calculates the tax formula, the effective tax rate starts at 186% of total sales and increases up to 1,900% of total sales.

as there are no similar fines elsewhere in Medicare. A company could avoid the tax by pulling all products for sale in federal programs, which would be a staggering and cruel health loss for America.

## Congress Fundamentally Changed How Government Relates to People

While most businesses are seeking to provide more transparency and accountability for their customers, the Biden Administration's implementation of the IRA moves in the opposite direction. Under Section 1198 of the law, Congress ***requires*** HHS to implement the negotiation law by "program instruction or other forms of program guidance" for 2026, 2027 and 2028.

This is not the regular process established by Congress to implement laws that encourages citizen participation in a transparent government for the people. Enacted in 1946, the Administrative Procedure Act (APA)[3] ensures citizens have a right to be heard by government, that government responds to their concerns, and that parties harmed by government have access to recourse. The APA includes requirements on Federal Agencies for informing the public of proposed and final rulemaking in the Federal Register, the opportunity for the public to comment, and a requirement to substantively address comments in any final rule. A key goal of the APA is to ensure disclosure of information that is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government.

The author of the APA, Senator Pat McCarran (D-NV), called the APA, "…a bill of rights for the hundreds of thousands of Americans whose affairs are controlled or regulated by federal government agencies".[4] As the U.S. General Services Administration has noted, "The APA ensures public transparency in the rulemaking process, while holding the government accountable to address public input. Transparency and accountability ensure integrity throughout the process."[5]

[3] Administrative Procedure Act | Wex | US Law | LII / Legal Information Institute (cornell.edu)
[4] The Decision of 1946: The Legislative Reorganization Act and the Administrative Procedure Act - The George Mason Law Review (gmu.edu)
[5] Celebrating the 75th anniversary of the Administrative Procedure Act | GSA

Using sub-regulatory guidance, as required by the IRA, circumvents other, well-established, normal processes that are beneficial when implementing programs. Executive Orders 12866 and 13563 (Clinton 1993, Obama 2011) give directives to Departments to create a regulatory framework that protects "…public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation." To comply with these requirements, the Department of Health and Human Services analyzes the benefits, costs, and other impacts of significant proposed and final rulemakings. According to HHS, regulatory impact analysis, "…provides an objective, unbiased assessment that is an essential component of policy development, considering both quantifiable and unquantifiable impacts. Along with information on legal requirements, general policy goals, the distribution of the impacts, and other concerns, it forms the basis of the ultimate policy decision."[6]

No RIA was issued when CMS produced its final program guidance.

Section 1198 also exempts from Administrative or Judicial review the following sections:

- Determination of a unit of a drug;
- The selection of drugs for price controls;
- Determination of the "Maximum Fair Price" or the price control; and
- Which drugs are eligible for "re-negotiation" under the program.

What this means in practice is there is no venue to appeal to the government for a change to the drug definition, whether a drug is on the list, what the price limit may be (even if the limit is clearly unreasonable) and when a product may be re-negotiated. The law simply shuts down further discussion, and vests powers squarely in the hands of government bureaucrats and politicians.

[6] HHS_RIAGuidance.pdf

Congress should amend Section 1198 of the Inflation Reduction Act to require the normal rulemaking process under the Administrative Procedure Act in implementing the Inflation Reduction Act's drug price negotiation program. The need to shield CMS decision-making process from scrutiny will erode public confidence in the price-setting process and in government in general.

## $3 Billion in New Federal Employees

Section 11004 appropriates $3 billion to CMS to implement the Drug Price Program. The Agency has announced six new divisions and job openings for 200 new positions to implement the program, but we also know CMS repurposed staff to fill immediate needs in standing up the program. This raises significant concerns and several questions, including:

- How is CMS spending the $3 billion?
- How many bureaucrats are required to implement this program?
- Are these new employees, or repurposed employees?
- Who is CMS hiring and what expertise do they have?
- If new employees came from industry, will CMS preclude employees from being lobbied by their former employers?
- How will real or perceived conflicts of interest be resolved?
- Considering the government is now implementing functions previously conducted by private sector actors, how many private sector jobs will be lost?

The Biden Administration should answer these questions, but a good, general rule, should be that in the process of governing, the government should not compete with its citizens.[7]

[7] OMB Circular A-76 (whitehouse.gov)

## Program Guidance

*Stakeholder Engagement*

Although it was not required, CMS took the trouble to release a ***draft*** sub-regulatory guidance to implement the program on March 15, which solicited feedback from stakeholders.[8] Then on June 30, CMS released final program guidance in accordance with the IRA law.[9] The 193-page document makes multiple references to soliciting stakeholder feedback, but there is no requirement on CMS to meet with anyone, consider comments, or respond to them.

CMS has scheduled several "stakeholder listening sessions" this fall and has noted that the sessions are each 1.5 hours long, and "subject to change, including postponement and/or cancellation."[10] Patient engagement should not be a check the box exercise. Congress should require patient representation on P&T committees, and any advisory committee considering cost effectiveness should include patient and clinical representatives.

*Program Guidance Written on Cocktail Napkins*

Because there is no formal process, CMS can rewrite the rules; the Agency could change the sub-regulatory document on a whim as if the rules were written on cocktail napkins. This creates incredible uncertainty in the market, and guides decisions about investment in new products to treat disease. In general, more uncertainty leads to less investment, and less investment leads to fewer products to treat or cure disease.

*Small Biotech Exception*

The IRA allows drug companies to submit requests to CMS for drugs that might qualify for the law's small biotech exception. CMS determined four companies qualified, but we do not know how many applied, how many applications were rejected and why, and who received the four

[8] Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments (cms.gov)
[9] Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (cms.gov)
[10] Factsheet: Medicare Drug Price Negotiation Program (cms.gov)

exceptions. This is valuable information that could guide other companies seeking to navigate the law's complexity, avoid business-killing price controls, and grow the patient population they serve.

## Medicare Drug Price Control List

Despite several lawsuits challenging the program[11], HHS is moving forward with implementation of 10 drugs subject to price controls in 2026. On August 29, 2023, CMS released its initial selected drug list for the program, and analysts have been scratching their heads ever since wondering why some of the drugs ended were selected. CMS states it was just "following the law," but the secrecy in the law provides little insight beyond that.

| Drug Name | Commonly Treated Conditions | Total Part D Gross Covered Prescription Drug Costs from June 2022-May 2023 | Number of Medicare Part D Enrollees Who Used the Drug from June 2022-May 2023 |
|---|---|---|---|
| Eliquis | Prevention and treatment of blood clots | $16,482,621,000 | 3,706,000 |
| Jardiance | Diabetes; Heart failure | $7,057,707,000 | 1,573,000 |
| Xarelto | Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease | $6,031,393,000 | 1,337,000 |
| Januvia | Diabetes | $4,087,081,000 | 869,000 |
| Farxiga | Diabetes; Heart failure; Chronic kidney disease | $3,268,329,000 | 799,000 |
| Entresto | Heart failure | $2,884,877,000 | 587,000 |
| Enbrel | Rheumatoid arthritis; Psoriasis; Psoriatic arthritis | $2,791,105,000 | 48,000 |
| Imbruvica | Blood cancers | $2,663,560,000 | 20,000 |
| Stelara | Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis | $2,638,929,000 | 22,000 |
| Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill | Diabetes | $2,576,586,000 | 777,000 |

Note: Numbers are rounded to the nearest thousands.

*For the time period between June 1, 2022 and May 31, 2023, which is the time period used to determine which drugs were eligible for negotiation, about 8,247,000 people with Medicare Part D coverage used these drugs to treat a variety of conditions, such as cardiovascular disease, diabetes, autoimmune diseases, and cancer. These selected drugs accounted for $50.5 billion in total Part D gross covered prescription drug costs, or about 20% of total Part D gross covered prescription drug costs during that time period.*

- First with respect to insulin which is already capped in Medicare at $35 a month, CMS bundled all sales across units with the same moiety but under different NDAs. The Agency needed to bundle the insulins to reach the sales threshold to make them all

[11] ira-litigation-tracker-table.pdf (goodwinlaw.com)

eligible for price regulation. It is unclear why CMS did this, but one can infer politics played a role.

- Several of the products on the list have near term generic competition coming on the market, perhaps before 2026. Why would CMS include these products if the price controls will only apply for a brief time or perhaps not at all?

The law also drives strange outcomes in terms of the list.

- The IRA and CMS ignore therapeutic competitors, where two branded products compete for the same patients because their product treats the same indication. For example, on this list are apixaban (Eliquis) and rivoraxaban (Xarelto), two direct oral anticoagulants that compete in the market. Also on the list are empagliflozin (Jardiance) and dapagliflozin (Farxiga), two SGLT2-inhibitors that recently received follow-on indications for their efficacy in heart failure. In the market, when there are two or more competitors, we see lower prices. Under the IRA, only generic competition counts in getting off the price control list. This shows a fundamental misunderstanding and perhaps distrust of how markets work to drive down prices. It will create long-term damage to keeping costs lower as brand-to-brand competition may erode for fear of price controls.

- Eliquis made the list even though it is 540th on Medicare net spend per patient at an average Medicare cost of $45 per patient per month. This is because 3 million people utilize the drug, which makes the gross Medicare spend high. Gross spending is what determines placement on the list, and appears to benefit taxpayers first, and patients maybe. A more logical approach would be to assess net cost per patient.

There are other questions surrounding the list, including whether HHS conducted research to know the effects of the policy on new drug development, attempted to determine the impact on specific indications such as cancer and Alzheimer's, or assessed the impact on seniors' timely

access to new treatments. If so, it would be important to know the results of the agency's analysis as well as any steps CMS took to minimize potential negative impacts on patients and innovation. If CMS did not undertake such an analysis, why not? These questions are a byproduct of the legal secrecy involved in shielding politicians and federal bureaucrats and the decisions they are making.

## Impact of the IRA

Most politicians only point out the benefits of new programs; politicians rarely will be honest enough to explain the tradeoffs inherent in most policy choices. While the IRA has or will achieve much good (the cap on insulin for Medicare patients; smoothing patient annual costs throughout the year; an annual limit on out-of-pocket drug spending), there are, of course, downsides.

### *Higher Prices, More Subsidies*

For example, this year the law requires manufacturers to pay rebates if they increase prices faster than inflation. Politicians tout reduced beneficiary coinsurance on the lower, inflation adjusted rate. But CBO estimates drug manufacturers will respond to inflation rebates with higher launch prices, and that taxpayers will provide $40 billion to insurers to stabilize and subsidize premiums for expanded benefit costs.[12]

### *Less R&D and Innovation, Fewer Treatments and Cures*

All experts (CBO, CMS, and private analysts) agree that there will be fewer products developed to treat or cure disease because of the IRA; they simply disagree on the extent of the damage. For example, CBO estimates that under the law, the number of drugs that would be introduced to the U.S. market would be reduced by about 2 over the 2023-2032 period, about 5 over the subsequent decade, and about 8 over the decade after that. [13] Vital Transformation, a private modeling firm, estimated that 139 drugs that will not be developed.[14] What we know is that even

[12] Additional Information About Prescription Drug Legislation (cbo.gov)
[13] Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation | Congressional Budget Office (cbo.gov)
[14] IRA's Impact on the US Biopharma Ecosystem - Vital Transformation

before price controls take effect, investment into new therapies and cures is shifting and, for certain products, ending.[15,16,17]

*Small Molecule Penalty Will Lead to (Surprise!) More Biologics, Worsen Health Disparities*

The legislation subjects traditional "small-molecule" drugs (pills) to price controls just nine years after FDA approval and subjects large-molecule "biologic" therapies to price controls after 13 years. This provision is already leading biotech companies to shift their research and development efforts away from small-molecule drugs. [18,19]

Large molecule drugs are injected or infused in a doctor's office or hospital. Medicare's cost-sharing arrangements require patients to pay something for both the administration of the drug and the drug itself. As a result, a shift towards large-molecule drugs will drive up out-of-pocket costs for patients and taxpayers. Overall costs may also rise because generic biologics – known as "biosimilars" – are more difficult and costly to make than small-molecule generics and take longer to hit the market. Small-molecule drugs often give patients the option of taking their medicine in the comfort of their own homes, and are especially important for rural, low-income, and minority patient communities who may lack access to local doctors, clinics, and hospitals. As a result, the small molecule penalty will worsen health disparities and health equity. Finally, small molecule drugs can enter cells and can cross the blood-brain barrier, making them important treatment options for many patient groups, including those living with certain cancers and neurological conditions. Fewer small molecule drugs means less treatments for these patients.

Fixing the IRA to put small-molecule and biologic drugs on the same, 13-year timeline would help prevent the law's unintended consequences and ensure continued research into new treatments and cures, regardless of whether they are small or large molecules.

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[15] UPDATE 1-Roche: have abandoned some trials due to U.S. drug pricing plans (yahoo.com)
[16] Inflation law drives biologic drugs to outpace small molecules in US venture financing (biopharma-reporter.com)
[17] Life Sciences Investment Tracker (incubatecoalition.org)
[18] Inflation law drives biologic drugs to outpace small molecules in US venture financing (biopharma-reporter.com)
[19] Life Sciences Investment Tracker (incubatecoalition.org)

*Orphan Drug Act*

The rare disease community recently commemorated the 40th anniversary of the enactment of the Orphan Drug Act (ODA) into law. Prior to the ODA, there was little interest or incentive for the biopharmaceutical industry to develop medications for rare diseases. Since the enactment of the ODA, more than 1,100 orphan designated approvals for treatment of rare diseases and disorders have been issued by the FDA. While this is encouraging, there is still much work to be done. 95 percent of the more than 10,000 rare diseases and disorders still lack an FDA-approved treatment. Developing treatments remains an extremely challenging and risky endeavor for the biopharmaceutical industry.

While the IRA includes a provision that exempts a product approved to treat a single rare disease or condition from Medicare's price negotiations, the exemption is too narrow. This will undoubtedly negatively impact any considerations a biopharmaceutical company might have of evaluating an approved rare disease drug for a potential second or third application to another rare disease or condition. The IRA harms the same patients it intends to help. This provision of the IRA must be amended to provide for a more realistic exemption standard.

## Solutions

We all want lower health costs. In many ways, we fundamentally disagree on the best way to achieve savings. Some want the government to be much more involved in health decisions. Based on decades of experience in other countries that is the wrong way to go as it will decrease access and drive up costs in the long term. To lower the cost of prescription drugs without harming access or innovation, Congress should:

1. *Stop Raiding Medicare.* Medicare is not a piggy bank – it is an important program that must be sustained for the future. The IRA cut Medicare by some $286 billion to fund the Green New Deal, Obamacare subsidies, and other projects. Medicare has become a piggy bank even as Medicare's finances worsen with the aging of society. A good rule of thumb

should be that Medicare savings should improve the Medicare program, the fiscal financial outlook, or both.

2. *Address very high cost products.* Innovative, curative, and expensive products are increasingly coming to market. As a society, we should celebrate cures for hemophilia, sickle cell disease, blindness, and cancer, but Congress must reform laws that prevent patients from affording these products. The bipartisan MVP Act (H.R. 2666[20]) propels payment innovation by removing federal barriers to allow state Medicaid programs, private payers, and manufacturers to enter into value-based purchasing arrangements (VBPs) for prescription drugs. Taxpayers and patients will save money by ensuring payment is only made if the drug works. States should be allowed to establish Medicaid purchasing pools to help spread costs, as the Biden Administration has proposed.[21]

3. *Get more products on the market faster.* When a therapeutic class of drugs has limited competition or one branded drug in a class, there is no countervailing market force to keep costs down. Brand-to-brand competition is a critical factor in keeping prescription drug costs low. Once competing drugs are available in a class, prices and net costs decrease, resulting in lower costs for patients, taxpayers, and employers. Congress should grant authority to the FDA commissioner to expedite approval of a branded drug where there is limited or no competition in a class. Congress should eliminate drugs with therapeutic competition from the Medicare Drug Price program.

4. *Lower the cost of clinical research.* Up to 40 percent of the cost of developing a drug comes in the initial stages. If clinical research were less expensive, final drug prices would be lower. Congress should make it easier to participate in clinical trials in the community, including through virtual trial participation, and create safe harbors for diversity in clinical trial participation. Congress should also create incentives to accelerate the use of AI in drug discovery.

[20] Text - H.R.2666 - 118th Congress (2023-2024): MVP Act | Congress.gov | Library of Congress
[21] A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans (cms.gov)

5. *Expand Competition Where it is lacking.* Several existing federal programs create higher reimbursement or provide price discounts to large service providers that are not available to community based physicians. Policy driven economics has caused many community based physicians to sell their practices to larger clinics or hospitals, increasing patient and taxpayer costs. Congress should create level playing fields to allow robust competition regardless of care setting.

6. *Empower Consumers.* Providing consumers with information, real time, about their drug costs and any required utilization management (such as step therapy) as required in the Transparency in Coverage Rule will help drive selection of lower cost alternatives. Requiring electronic (not paper) prior authorization will speed approval of therapies and should be done across all federal programs. Combining transparency with financial incentives, such as premium discounts or cash back into an HSA, would create powerful incentives to lower costs.

7. *Repeal the IRA Drug Price Program.* The Medicare Drug Price Program is fundamentally flawed. It promotes secrecy and political decision-making about intimate and personal health matters. The law negatively impacts innovation, and ultimately raises costs while exacerbating health disparities. Congress should repeal the program and start over.

## Conclusion

As the Inflation Reduction Act is implemented, Congress must ensure the administration is held accountable for good outcomes and is acting in the best interests of taxpayers and Medicare beneficiaries. That will be difficult to achieve considering the layer of secrecy that shrouds decision making and the suspension of due process authorized by Congress. The precise impact of the law on new therapies and cures, patient access, innovation, and costs is not fully understood, but we know creating an environment where scarcity can thrive is rarely successful.

Thank you for the opportunity to testify, and I am happy to answer any questions.