ENERGY & COMMERCE
CHAIR RODGERS

MEMORANDUM

To: Members and Staff, Subcommittee on Oversight and Investigations

From: Majority Committee Staff

Re: Hearing on "IRA Implementation"

The Subcommittee on Oversight and Investigations will hold a hearing on Wednesday, September 20, 2023, at 2:00 p.m. (ET). The hearing will take place in 2123 Rayburn House Office Building. The hearing title is "At What Cost: Oversight of How the IRA's Price Setting Scheme Means Fewer Cures for Patients."

I. WITNESSES

- Mr. John Czwartacki, Founder
  Survivors for Solutions

- Dr. Steve Potts, Ph.D., MBA
  Chair, Drug Development Council
  International Cancer Advocacy Network

- Mr. John Crowley, Executive Chairman
  Amicus Therapeutics, Inc.

- Dr. Aaron S. Kesselheim, M.D., J.D., M.P.H.
  Professor of Medicine at Harvard Medical School, Director, Program on Regulation, Therapeutics, And Law (PORTAL), Brigham and Women's Hospital

II. OVERVIEW

The hearing will provide an opportunity for members of the Committee to learn more about how Center for Medicare and Medicaid Services' (CMS) implementation of the Drug Price Negotiation Program, established by the Inflation Reduction Act (IRA), will result in fewer lifesaving cures and treatments and negative outcomes for patients battling serious and life-threatening diseases.

III. BACKGROUND

Overview of the Inflation Reduction Act's Drug Price Negotiation Program

On August 16, 2022, President Biden signed the IRA into law following its earlier passage through Congress on a party line vote via the budget reconciliation process.[1] Among other provisions, the IRA authorizes the Secretary of the Department of Health and Human Services (HHS) to negotiate prices with manufacturers.[2] Drugs eligible for negotiation are those that have high total spending and high Medicare Part B and Part D expenditure and are single source drugs without generic or biosimilar competition.[3] To be eligible for negotiation, drugs must have been on the market for at least seven years for small molecule drugs and 11 years for biologics.[4]

Under the IRA, each year the Secretary, in a process implemented by CMS, selects a statutorily specified number of negotiation eligible drugs.[5] This process began for the first time on August 29, 2023, when Secretary Becerra announced the first ten negotiable drugs.[6] In 2027, the number of drugs selected annually for negotiation will expand from 10 to 15. In 2029, that number will increase to 20 drugs annually.[7] Until 2028, only Part D drugs are eligible for negotiation. After 2028, Part B drugs are also negotiation eligible.[8] The number of drugs selected for negotiation is cumulative. By 2029, 50 drugs will have been selected for negotiation.

The IRA's Price Negotiation Program is not an arms-length negotiation. In fact, the price setting process is not consistent with commonly accepted definitions of "negotiation."[9] The maximum price for a selected drug is statutorily capped at 25% to 60% below the non-Federal average manufacturer price (market price).[10] Beyond that price ceiling, the Secretary has broad

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[1] Kirkland & Ellis, *The Inflation Reduction Act is Signed into Law by President Biden: Key Energy and Infrastructure Provisions*, Kirkland & Ellis (Aug. 16, 2022), https://www.kirkland.com/publications/kirkland-alert/2022/08/the-inflation-reduction-act-is-signed-into-law-by-president-biden.
[2] Juliette Cubanski et al., Explaining the Prescription Drug Provisions in the Inflation Reduction Act, KFF (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.
[3] ASPE, Inflation Reduction Act Research Series: Medicare Enrollees' Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price Negotiation Program, ASPE (Aug. 29, 2023), https://aspe.hhs.gov/reports/aspe-ira-drug-negotiation-fact-sheet.
[4] 42 U.S.C. § 1320f-1(a)(1) (2022).
[5] *Supra*, note 2.
[6] Jared S. Hopkins & Stephanie Armour, *Expensive Drugs Targeted for First U.S. Price Negotiations*, Wall St. J. (Aug. 29, 2023), https://www.wsj.com/health/pharma/expensive-drugs-from-pfizer-other-companies-targeted-for-first-u-s-price-negotiations-9942b20b.
[7] *Supra*, note 2.
[8] *Id.*
[9] Merriam-Webster defines negotiation as "to arrange for or bring about through conference, discussion, and compromise." *Negotiation*, Merriam-Webster's Dictionary, https://www.merriam-webster.com/dictionary/negotiate#:~:text=%3A%20to%20arrange%20for%20or%20bring,negotiate%20a%20treaty.
[10] 42 U.S.C. § 1320f-3(e)(1),(2) (2022); *see also* Centers for Medicare and Medicaid, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026*, (Jun. 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf [hereinafter CMS Guidance].

discretion in setting a price and may use practically any information deemed relevant to determine the price that will be paid for a select drug.[11] A unique feature of the "negotiations" is that manufacturers must agree to accept that price *before* negotiations begin.[12] As discussed below, the penalties for refusing to negotiate and to agree in advance to accept CMS's price setting determination are extremely punitive.

Drug Name	Commonly Treated Conditions
Eliquis	Prevention and treatment of blood clots
Jardiance	Diabetes; Heart failure
Xarelto	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease
Januvia	Diabetes
Farxiga	Diabetes; Heart failure; Chronic kidney disease
Entresto	Heart failure
Enbrel	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis
Imbruvica	Blood cancers
Stelara	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Diabetes

Figure 1: Drugs Selected for Negotiation in 2023 with Initial Price Applicability in 2026. Source: https://www.bassberry.com/news/cms-announces-10-drugs-selected-for-medicare-negotiation-in-2026/

Another unusual feature of the Price Negotiation Payment is its lack of procedural due process protections and prohibition on judicial review. A manufacturer likely cannot go to court to challenge the price CMS dictates for one of its drugs. The IRA took the extreme step of exempting most aspects of the Price Negotiation Program from judicial review.[13] The

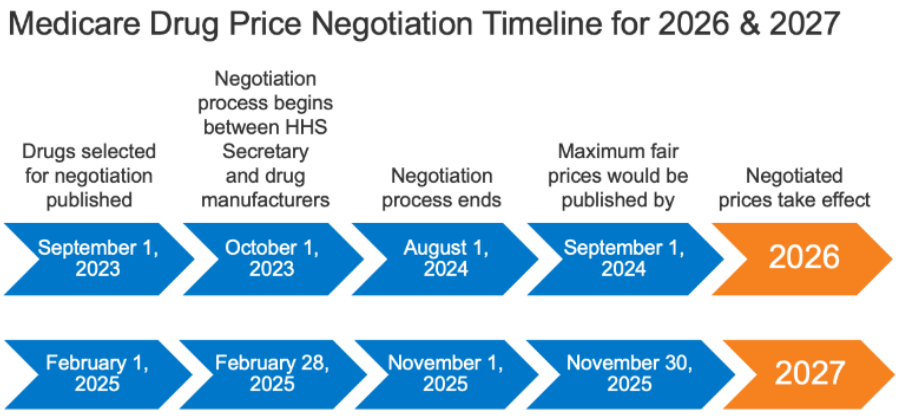

Figure 2: Implementation Timeline for Price Negotiation Program. Source:https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/

[11] *Id.*
[12] 42 U.S.C. § 1320f-2(a) (2022).
[13] 42 U.S.C. § 1320f-7 (2022).

implementation of the program is also exempt from notice and comment rulemaking typically required for government actions of this magnitude.[14] CMS's policymaking process and drug price deliberations are also exempt Freedom of Information Act requests.[15] The IRA also bars manufacturers from publicly releasing any information about the negotiations or CMS will consider any information submitted to it by the company to be no longer proprietary.[16] While the IRA exempted certain kinds of drugs and certain size companies from negotiation, the Secretary has broad discretion in interpreting those exemptions. In most instances, HHS has adopted a narrow interpretation of exemptions.

If a drug manufacturer refuses to enter into an agreement to participate in the Price Negotiation Program or subsequently does not agree to the price set by CMS, the company subject to an excise tax penalty of as much as to 19 times the daily gross sales of the selected drug nationwide.[17] A company can only avoid the excise tax by removing all of its drugs from coverage by Medicare and Medicaid, not just the drug selected for negotiation.[18]

Moreover, CMS has made clear that manufacturers are responsible not only for ensuring their own compliance with the price setting agreement but are also responsible for ensuring that entities dispensing a negotiated drug are complying with the agreement.[19] The civil monetary penalties that a manufacturer faces for noncompliance include a penalty ten times the amount of any rebate that the manufacturer failed to pay and a $1,000,000 a day penalty for failing to comply with CMS demands for information or the terms of a price setting agreement.[20]

Constitutional Challenges to the Price Negotiation Program

The Price Negotiation Program is a bureaucratic and punitive approach to trying to lower drug prices. The process of its implementation had led to tremendous uncertainty among manufacturers and drug developers. CMS has yet to release guidance for many key provisions of the program.[21] It is anticipated that long-term, the Price Negotiation Program will lead to, among other things, higher insurance premiums in the commercial market (which insures 66.5% of Americans) and, ironically, higher list prices for prescription drugs.[22]

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[14] *Id.*
[15] CMS Guidance, *supra* note 10, at 123-124.
[16] *Id.*
[17] Complaint at 5, Dayton Area Chamber of Com. v. Becerra, No. 3:23-cv-00156-TMR-PBS, (S.D. Ohio June 9, 2023), https://www.uschamber.com/assets/documents/Complaint-Dayton-Area-Chamber-of-Commerce-v.-Becerra-S.D.-Ohio.pdf.
[18] *Id.*
[19] CMS Guidance, *supra* note 10, at 170-174.
[20] 42 U.S.C. § 1320f–6(b),(c) (2022).
[21] Hannah-Alise Rogers, Cong. Research Serv., R47555, Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations (2023), https://www.crs.gov/Reports/R47555?source=search#ifn135.
[22] Katherine Keisler-Starkey and Lisa N. Bunch, *Health Insurance Coverage in the United States: 2020*, U.S. Census Bureau (Sept. 14, 2021), https://www.census.gov/library/publications/2021/demo/p60-274.html; Brett Christie, *How Does the Inflation Reduction Act Affect Private Employer Health Benefits?*, WorldatWork (Aug. 19, 2022), https://worldatwork.org/resources/publications/workspan-daily/how-does-the-inflation-reduction-act-affect-private-employer-health-benefits-; Letter from Phillip L. Swagel, Director, Cong. Budget Office, to the Honorable

The provisions of the Price Negotiation Program are so punitive that several of the impacted drug developers and related trade associations have sued on constitutional grounds:

- **Uncompensated Takings & Due Process (Fifth Amendment)**: Several manufacturers, alleged that the Price Negotiation Program constitutes an unconstitutional taking of their property without adequate compensation or due process. [23]

- **Compelled Speech (First Amendment)**: The U.S. Chamber of Commerce and several manufacturers allege that the IRA compels companies to endorse publicly government-set prices, using specific terms like "agreement," "negotiation," and "Maximum Fair Price."[24]

- **Excessive Fines (Eighth Amendment)**: Several plaintiffs have alleged that the IRA's "excise tax" violates the Eighth Amendment's prohibition on excessive fines as a penalty of up to nineteen times a company's nationwide revenue is disproportionate to the government's regulatory interest.[25]

- **Unconstitutional Conditions on Participation**: Several manufacturers allege that the IRA coerces companies to surrender their rights under First and Firth Amendments as a condition participation in Medicare and Medicaid.[26]

The most devastating effects of the IRA's Price Negotiation Program will be felt in its impact on drug research and development and the patients relying on innovation for treatments and cures.

Impact on Patients and the Cures Pipeline

Even the most analytically conservative assessments of the Price Negotiation Program have concluded that it will negatively impact the development of new treatments and cures. For example, the Congressional Budget Office's (CBO) review of the IRA concluded that the Price

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Jason Smith, Ranking Member, U.S. House Comm. on the Budget (Aug. 4, 2022), https://www.cbo.gov/system/files/2022-08/58355-Prescription-Drug.pdf.

[23] Complaint at 3, Bristol Myers Squibb Co. v. Becerra, No. 3:23-cv-03335, (D. N.J. June 16, 2023), https://storage.courtlistener.com/recap/gov.uscourts.njd.513814/gov.uscourts.njd.513814.1.0.pdf; Complaint, AstraZeneca Pharm. LP v. Becerra, No. 1:23-cv-00931-UNA, (D. Del. Aug. 25, 2023), https://www.courtlistener.com/docket/67728615/astrazeneca-pharmaceuticals-lp-v-becerra/.

[24] Complaint, Astellas Pharma U.S., Inc. v. Becerra, 1:23-cv-04578, (N.D. Ill. July 14, 2023), https://www.courtlistener.com/docket/67610373/astellas-pharma-us-inc-v-department-of-health-and-human-services/; Dayton Area Chamber of Com., No. 3:23-cv-00156-TMR-PBS, *supra* note 17.

[25] Complaint, Novartis Pharm. Corp. v. Becerra, No. 2:23-cv-14221, (D. N.J. Sept. 1, 2023), https://storage.courtlistener.com/recap/gov.uscourts.njd.526368/gov.uscourts.njd.526368.1.0.pdf.

[26] Complaint, Janssen Pharm., Inc. v. Becerra, No. 3:23-cv-03818, (D. N.J. July 18, 2023), https://www.courtlistener.com/docket/67615510/janssen-pharmaceuticals-inc-v-becerra/; Complaint, Boehringer Ingelheim Pharm., Inc. v. U.S. Dep't Health & Human Serv., No. 3:23-cv-01103, (D. Conn. Aug. 18, 2023), https://www.courtlistener.com/docket/67706159/boehringer-ingelheim-pharmaceuticals-inc-v-united-states-department-of/.

Negotiation Program will result in only 13 fewer new drugs coming to market over the course of 30 years.[27]

In this regard, the CBO is an outlier. Other analysis and financial announcements from drug developers suggests that the impact on the number of new drugs brought to market will be much greater. One study concluded that, as a result of the substantial reduction in revenue caused by the Drug Price Negotiation Program, an estimated 139 drugs over a ten-year period were at risk of not being developed.[28] The same survey calculated that had the program been in place in 2014, between 24 and 39 treatments currently available would not have been developed.[29]

A survey of oncology drug development stakeholders found that 76% of those surveyed reported seeing reductions in funding for the development of small molecule drugs as a result of the IRA's provision making small molecule drugs negotiation eligible after only 9 years.[30] Similarly, Committee staff have identified at least 24 instances in which a drug developer announced that it was canceling, delaying, or were otherwise reconsidering a treatment under development because of the Price Negotiation Program.[31]

The Price Negotiation Program's impact on the development of new cures and treatments is expected to be so great because drug development is a high-risk endeavor where a small number of commercially successful drugs compensate for a much larger number of unsuccessful developments. Some 90% of potential treatments that enter Phase I trials fail.[32] As one academic paper noted, "[n]o other major business type operates under such a high failure rate".[33] It takes on average ten years and up to $10 billion to develop a new drug.[34] In 2021, drug industry spending on research and development was over $100 billion .[35] By reducing revenue from successful drugs by up to as much as 40%, the IRA upends the entire biopharmaceutical ecosystem and disincentivizes investment in drugs.[36]

Small molecule drugs, typically taken as pills and used to treat serious diseases including multiple cancers, cystic fibrosis, and Alzheimer's, are particularly impacted because they are

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[27] Cong. Budget Office, Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation (2022), https://www.cbo.gov/system/files/2022-07/senSubtitle1_Finance.pdf, at 5.
[28] Daniel Gassull et al., *IRA's Impact on the US Biopharma Ecosystem*, Vital Transformation (June 1, 2023), https://vitaltransformation.com/wp-content/uploads/2023/06/VT-BIO_IRA_v12.2.pdf.
[29] *Id.*
[30] Steve Potts, *Saving Money for Medicare by Abandoning New Drugs for Medicare Patients*, Rapport (Sept. 21, 2022), https://rapport.bio/all-stories/ira-abandoning-new-cancer-drugs-for-medicare-patients.
[31] Report on file with Committee staff.
[32] Derek Lowe, *The Latest on Drug Failure and Approval Rates*, Science (May 9, 2019), https://www.science.org/content/blog-post/latest-drug-failure-and-approval-rates.
[33] *Id.*
[34] Cong. Budget Office, Research and Development in the Pharmaceutical Industry (2021), https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.
[35] Matej Mikulic, *Research and Development Expenditure of Total U.S. Pharmaceutical Industry from 1995 to 2022*, Statista (Aug. 25, 2023), https://www.statista.com/statistics/265085/research-and-development-expenditure-us-pharmaceutical-industry/.
[36] Daniel Gassull, *supra* note 28.

subject to price negotiation after only nine years as compared to thirteen years for biologics.[37] This is expected to shift reserach and development funding towards biologics, which are generally priced higher and more expensive and intrusive to administer, not because of a change in the underlying science but because of a change in incentives resulting from the IRA.[38] The IRA also provides a strong negative incentive to biologic and generic companies seeking to introduce low price alternatives to branded drugs because CMS' price setting greatly reducing their products ability to beat branded drugs on price.[39]

The Price Negotiation Program also negatively impact the incentives that drive the development of drugs used to treat rare diseases, known as "orphan drugs." CMS has interpreted the IRA's orphan drug exemption as only applying to single indication, so a manufacturer loses the exemption if they seek a second orphan drug indication.[40] Similarly, the IRA discourages companies from developing multiple closely related drugs that target the same disease through different mechanisms because of uncertainty regarding how CMS will determine the value such treatments.[41]

IV. KEY QUESTIONS

1. The IRA's Price Negotiation Program represents a specific public policy tradeoff, fewer new treatments and cures (along with higher drug list prices and private insurance premiums) in exchange for lower drug prices for Medicare. Is this tradeoff a net positive in terms of broader health care outcomes? How can Congress work to mitigate the worst impacts of the IRA's Price Negotiation Program on drug development?

2. What changes has the IRA caused to the pharmaceutical landscape, especially in terms of research and development investments?

3. How can Congress ensure that innovations for rare diseases continues?

4. Given the absence of traditional notice and comment rulemaking, how did CMS and HHS take into account feedback from patient advocates, industry, and other stakeholders?

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[37] John Stanford, *Congress Must Fix the IRA's Small Molecule Penalty*, STAT News (Mar. 6, 2023), https://www.statnews.com/2023/03/06/congress-must-fix-ira-small-molecule-penalty/#:~:text=Under%20the%20IRA%2C%20the%20price,essential%20for%20recapturing%20their%20investment.

[38] Sophie Fessl, *How the IRA Will Affect Drug Development*, BioSpace (Apr. 6, 2023), https://www.biospace.com/article/how-the-ira-will-affect-drug-development/.

[39] Dana Goldman et al., *Mitigating the Inflation Reduction Act's Adverse Impacts on the Prescription Drug Market*, USC Schaeffer (Apr. 13, 2023), https://healthpolicy.usc.edu/research/mitigating-the-inflation-reduction-acts-potential-adverse-impacts-on-the-prescription-drug-market/.

[40] Rachel King & Peter L. Saltonstall, *The IRA Needs Changes to Better Support Patients with Rare Diseases*, STAT News (Sept. 13, 2023), https://www.statnews.com/2023/09/13/inflation-reduction-act-orphan-drugs-rare-diseases-cms/.

[41] John Czwartacki, *LTE: We Need Drug Choices, Published by the New York Times*, Survivors for Solutions (Aug. 10, 2023), https://www.survivorsforsolutions.org/news-and-updates/4yzfj8t9ki63spiiycfv7z8fen310n.

5. How have companies adjusted their strategic priorities, and what implications might this have for the broader health care landscape?

V. STAFF CONTACTS

If you have any questions regarding the hearing, please contact John Strom or Gavin Proffitt of the Subcommittee on Oversight and Investigations Majority staff at (202) 225-3641.