AN UNFORESEEN CONDITION: THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM AND ITS EFFECTS ON PHARMACEUTICAL RESEARCH, PRICING, AND ACCESS

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INTRODUCTION

Hemgenix is a revolutionary gene therapy for hemophilia B—it also costs $3.5 million for a one-time treatment.[1] While this is an extreme example of the costs of modern medicine, there are many other drugs with a five or six-digit price tag, and countless others that Americans cannot afford. Drug pricing and the public's inability to purchase these lifesaving medicines are growing national concerns. To combat this, the Inflation Reduction Act of 2022 (IRA) includes several provisions that aim to lower prescription drug costs for Medicare recipients and reduce federal spending on drugs.[2] In the Act, the Secretary of Health and Human Services (HHS) is required to negotiate prices with pharmaceutical companies for a set number of drugs covered under Medicare Parts B and D.[3] The Centers for Medicare and Medicaid Services (CMS) announced their list of the initial ten Part D drugs for negotiation on August 29, 2023.[4] A flurry of critique and litigation quickly followed.

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[1] Miryam Naddaf, *$3.5-Million Hemophilia Gene Therapy Is World's Most Expensive Drug*, NATURE (Dec. 9, 2022), https://www.nature.com/articles/d41586-022-04327-7.

[2] *See* KATHERINE M. KEHRES ET AL., CONG. RSCH. SERV., R47396, HEALTH CARE PROVISIONS OF THE BUDGET RECONCILIATION MEASURE P.L. 117-169 11 (2023) (detailing the Medicare provisions of the Act).

[3] 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/.

[4] CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: SELECTED DRUGS FOR INITIAL PRICE APPLICABILITY YEAR 2026, (Aug. 2023), https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf [hereinafter SELECTED DRUGS]; Sheryl Gay Stolberg & Rebecca Robbins, *U.S. Announces First Drugs Picked for Medicare Price Negotiations*, N.Y. TIMES (Aug. 29, 2023), https://www.nytimes.com/2023/08/29/us/politics/medicare-drug-pricing-negotiations.html.

Lowering prices on prescription drugs is a worthwhile government interest, but the current approach will produce unintended and negative consequences in drug research and access. By only negotiating over a small list of high-spending drugs each year, HHS and CMS will continuously inject uncertainty into an extremely regulated and cost-conscious market. The yearly specter of negotiation and significant penalties for failure to reach an agreement will reduce incentives to invest and stymie development in the world's leading market for new drugs.[5] In turn, this limits supply and decreases treatment options as companies slow research or exit the market. Further, the act of negotiating on behalf of Medicare patients—a group not representative of the U.S. as a whole—will divert research and care from potential treatments that would benefit younger and underserved communities.

To prevent this scenario, HHS and CMS should minimize uncertainty in the negotiation program, and Congress must rapidly expand the scope of negotiations to quickly encompass all eligible drugs under Medicare Parts B and D. In addition, the government must act to directly combat private market drug costs as Medicare negotiations will not effectively lower prices for non-beneficiaries. While there are many suggested methods to do so, this paper will briefly highlight one such approach: increase Pharmacy Benefit Manager (PBM) transparency and require rebate passthroughs.[6]

Part II of this paper will explore the context, background, and structure of the Medicare Drug Price Negotiation Program (Program). It also describes the initial drug negotiation list and introduces related litigation. Part III will focus on the primary issues and ramifications of the Program, including decreased research and lower drug availability. Part IV discusses if Medicare is the proper platform for the government to combat high drug costs. Finally, Part V brings a proposal to decrease risk and uncertainty within the Program and encourages Congress to act outside of Medicare to more effectively lower drug prices for the population as a whole. The negotiations have begun, and unless the courts restrict or a prohibit the Program's implementation, its effects will soon be felt. By managing industry fears and increasing the scope of drug negotiations, the government can successfully balance robust drug research while lowering drug prices for Medicare and its beneficiaries.

I. HISTORY OF THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM

A. *Medicare and Part D Prescription Drug Coverage*

Medicare came into existence on July 30, 1965, when President Lyndon B. Johnson signed Title XVIII of the Social Security Act into law.[7] It was enacted to provide health coverage and enhance the financial security of Americans aged 65 and older who were underserved by employment-based insurance.[8] The original program included hospital coverage under Medicare

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[5] Between 2017-2022, 64.4% of new medicine sales were from the U.S. Market. Europe, the second-largest market only saw 16.4% of new medicine sales. EUR. FED'N OF PHARM. INDUS. & ASS'NS, THE PHARMACEUTICAL INDUSTRY IN FIGURES, KEY DATA 2023, 4 (2023), https://www.efpia.eu/media/rm4kzdlx/the-pharmaceutical-industry-in-figures-2023.pdf.

[6] Unaffordable drug pricing is caused by a myriad of factors, of which PBMs play a significant part. *See* Isaac D. Buck, *The Drug (Pricing) Wars: States, Preemption, and Unsustainable Prices*, 99 N.C. L. REV. 167, 170 (2020). The introduction of PBMs and proposed legislation within this paper is not meant to serve as a complete resource on the topic, but rather demonstrates one of many potential methods the federal government could successfully manage prescription drug costs. Citations referencing relevant legislation are provided, but a complete political and legal analysis is not directly addressed.

[7] *CMS' Program History*, CTRS. FOR MEDICARE & MEDICAID SERVS. (2023), https://www.cms.gov/about-cms/who-we-are/history. 42 U.S.C. §§ 1395–1395III.

[8] *The History of Medicare*, NATIONAL ACADEMY OF SOCIAL INSURANCE (2023), https://www.nasi.org/learn/medicare/the-history-of-medicare/.

Part A, and optional coverage for physician and outpatient services under Medicare Part B.[9] Medicare's services expanded over the following decades and it grew to cover the disabled as well as those with end-stage renal disease.[10] The Balanced Budget Act of 1997 (BBA) established Medicare Part C—later named Medicare Advantage—and authorized CMS to contract with private insurers to offer additional health plan options to beneficiaries.[11]

In 2003, the Medicare Prescription Drug Improvement and Modernization Act of 2003 brought sweeping changes.[12] It added Medicare Part D—an optional drug benefit through private plans who contract with CMS—which went into effect in 2006.[13] The prescription drug benefit has been highly utilized, and as of 2023, over 50 million of the 65 million covered by Medicare are enrolled in a Part D plan.[14] Part D utilizes premium payments with four benefit phases: the deductible, initial coverage, coverage gap, and catastrophic coverage.[15] The Part D Low-Income Subsidy program also provides eligible beneficiaries with "low incomes and modest assets" financial assistance towards deductibles and plan premiums.[16] Further, Medicare spending on prescription drugs is substantial and continues to grow.[17] Part D spending totaled $118 billion in 2022, and is predicted to hit $120 billion in 2023.[18] Increased out-of-pocket costs also burden Medicare beneficiaries, who often rely on limited or fixed budgets for their healthcare costs.[19]

B. *The Inflation Reduction Act and CMS Drug Price Negotiation Program*

The Inflation Reduction Act of 2022 includes several provisions aimed to help Medicare combat high prescription drug prices and lower costs for program beneficiaries.[20] One key measure in the IRA is Section 11001, which states the HHS Secretary must establish a Drug Price Negotiation Program to negotiate selected qualifying drugs and biologics dispensed to Medicare part D and part B enrollees.[21] To do so, the statute requires CMS to identify and publish a list of "qualifying single source, negotiation-eligible, selected drugs for price year 2026."[22] The baseline requirements of a qualifying "single source" drug are described within the Act, and initial CMS guidance on drug selection states they aim to target drugs without meaningful market competition, while also working to prevent drugmakers from avoiding negotiation via changes to their product labeling, dosing, or authorizing a generic version.[23] Qualifying biological products

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[9] *Id. See* 42 U.S.C. §§ 1395c, 1395k.
[10] *CMS' Program History*, *supra* note 7.
[11] *Health Plans – General Information*, CTRS. FOR MEDICARE & MEDICAID SERVS. (2023), https://www.cms.gov/medicare/enrollment-renewal/health-plans; *see* 42 U.S.C. § 1395w–22 (describing Benefits and Beneficiary Protections).
[12] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066.
[13] *CMS's Program History*, *supra* note 7.
[14] *An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 17, 2023), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit.
[15] *Id.*
[16] *Id.*
[17] CONG. BUDGET OFFICE, BASELINE PROJECTIONS, MEDICARE 2 (2023), https://www.cbo.gov/system/files/2023-05/51302-2023-05-medicare.pdf.
[18] *Id.*
[19] *See An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 14.
[20] Inflation Reduction Act of 2022, P.L. 117-169, 136 Stat. 118.
[21] KEHRES ET AL., *supra* note 2, at 10; *see* 42 U.S.C. § 1320f. The IRA acts as an exception to the original Part D statute's "noninterference" clause. The original clause states HHS and CMS (1) cannot interfere with negotiations between drug manufacturers, pharmacies, and PDP sponsors, and (2) cannot require a specific formulary or price structure for Part D drug reimbursement. 42 U.S.C § 1395w-111(j).
[22] 42 U.S.C. § 1230f-1(a)(1).
[23] *Id.* at § 1320f-1(e)(1)(A)(i)–(iii) (describing requirements of a qualifying single source drug); HANNAH-ALISE ROGERS., CONG. RSCH. SERV., R47555, IMPLEMENTATION OF THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM:

are similarly defined—but notably the IRA requires 11 years of market availability before those negotiations instead of only seven years for small-molecule drugs.[24] There are also multiple exceptions to qualifying single source drugs that include: orphan drugs, "low-spend" Medicare drugs, and plasma-derived products.[25] Finally, a statutory "small biotech drug" exception is enacted for years 2026 through 2028.[26]

Once the drugs are qualified, CMS reviews yearly drug costs through prescription drug event (PDE) data and identifies the 50 eligible drugs with highest Medicare Part D (and eventually Part B) spending.[27] The top ten spending drugs—or "selected drugs"—are published and subject to the initial negotiation for applicability in 2026.[28] The negotiations themselves are multifaceted, and involve a public data submission period, meetings with the company and public, an initial CMS offer containing a maximum fair price, a 30-day response period, and up to three follow up negotiations.[29] The maximum fair price (MFP) defines the upper limit for the negotiated price, and once negotiations conclude, the drugs are required to be covered under all Part D plans.[30] Medicare payments for Part B drugs will then be set at 106% of the MFP instead the current 106% of average sale price.[31] If the manufacturers fail to reach a compromise or otherwise do not comply with the negotiation process, an excise tax of 65% of the product's U.S. sales is applied.[32] The tax then increases 10% every quarter up to a maximum 95%.[33] Alternatively, the manufactures can choose to withdraw the drug from all Medicare and Medicaid coverage.[34] The program selects ten Part D drugs for negotiation to take effect in 2026, fifteen Part D drugs for 2027, fifteen Part D and Part B drugs for 2028, and continues indefinitely thereafter with twenty Part D and B negotiations for 2029 and after.[35]

C. *The Initial Program Selection List and Legal Challenges*

On August 29, 2023, CMS announced the initial ten drugs for negotiation. The selected drugs accounted for "$50.5 billion of Part D gross covered prescription drug costs," which is around 20%

CTRS. FOR MEDICARE AND MEDICAID GUIDANCE AND LEGAL CONSIDERATIONS 3 (2023); *see* CTRS. FOR MEDICARE & MEDICAID SERVICES SERVS., INITIAL MEMORANDUM:, IMPLEMENTATION OF SECTIONS 1191 – 1198 OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2026, AND SOLICITATION OF COMMENTS (Mar. 15, 2023), https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf [hereinafter CMS INITIAL GUIDANCE].

[24] 42 U.S.C. § 1320f-1(e)(1)(B)(i)–(iii) (defining qualifying single source biologics).

[25] CMS INITIAL GUIDANCE, *supra* note 23, at 10–12.

[26] 42 U.S.C. § 1320f-1(e)(3)(B).

[27] *Id.* § 1320f-1(b)(1)(A); CMS INITIAL GUIDANCE, *supra* note 23, at 5–6, 15.

[28] 42 U.S.C. §§ 1320f-1(a)(1), (c)(1); CMS INITIAL GUIDANCE, *supra* note 23, at 6.

[29] CTRS. FOR MEDICARE & MEDICAID SERVS., FACT SHEET: KEY INFORMATION ON THE PROCESS FOR THE FIRST ROUND OF NEGOTIATIONS FOR THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM (Sept. 2023), https://www.cms.gov/files/document/fact-sheet-negotiation-process-flow.pdf. For a detailed description of the negotiation process, *see* CTRS. FOR MEDICARE & MEDICAID SERVS., REVISED GUIDANCE:, IMPLEMENTATION OF SECTIONS 1191 – 1198 OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2026 20-21 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf [hereinafter CMS REVISED GUIDANCE].

[30] Cubanski et al., *supra* note 3.

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] *Id.*

of total Part D covered prescription costs.[36] These drugs, which include well-known brands such as Eliquis, Jardiance, and Xarelto, are used by millions of Part D beneficiaries.[37] HHS announced this as an important step to "increase[] availability and lower[] prescription drug costs for all Americans," and that the Program will allow Medicare to serve people now "and for generations to come."[38] HHS further explained the negotiations will consider multiple factors for each drug, including its clinical benefit, fulfilment of an unmet medical need, and its impact on those who rely upon Medicare, as well as costs associated with research and development.[39] This will allow Medicare beneficiaries to receive access to "innovative, life-saving treatments at lower costs to Medicare."[40]

But even before the initial list was made public, pharmaceutical companies filed lawsuits against the Program. These suits argue against the constitutionality of the negotiation provisions in various ways.[41] Though generally, the companies allege violations of the First or Fifth Amendment.[42] Lawsuits were initially filed by Merck, the U.S. Chamber of Commerce, Bristol Myers Squibb, the National Infusion Center Association, Astellas Pharma, Janssen Pharmaceuticals, Boehringer Ingelheim, and AstraZeneca.[43] Novartis later filed suit after their inclusion in the program, and Astellas voluntarily dismissed theirs after they were not selected in the 2026 list.[44] The drugmakers believe the Program is not a negotiation, because the only option is to accept the government's price, however, the Administration cites to significant legal precedent for this type of arrangement.[45]

Litigation is ongoing and its effects on the Program's future are uncertain.[46] Yet change is needed, as studies confirm that the U.S. spends far more per capita on prescription drugs than other developed nations.[47] The Congressional Budget Office (CBO) estimates the Program will lower the deficit by $25 billion, with significant decreases in Medicare Part D and B spending.[48] The program, if it can survive legal attacks, will provide large savings to Medicare and its Part D beneficiaries. However, these savings are not without major risks.[49]

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[36] Costs between June 1, 2022, and May 31, 2023. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: SELECTED DRUGS FOR INITIAL PRICE APPLICABILITY YEAR 2026 1 (Aug. 2023), https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf.
[37] *Id.*
[38] *HHS Selects the First Drugs for Medicare Drug Price Negotiation,* DEPT. OF HEALTH & HUMAN SERVS. (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.
[39] *Id.*
[40] *Id.*
[41] Noah Tong, *The Legal Battle Over Drug Price Negotiations Is Just Getting Started*, FIERCE HEALTHCARE (Sept. 13, 2023), https://www.fiercehealthcare.com/payers/legal-battle-over-drug-price-negotiations-just-getting-started.
[42] *Id. See* HANNAH-ALISE ROGERS, CONG. RSCH. SERV., R47682, CONSTITUTIONAL CHALLENGES TO THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM (Sept. 6, 2023).
[43] Tong, *supra* note 41.
[44] *Id.*
[45] *Id.*
[46] For updates on tracked litigation related to the Inflation Reduction Act, *see Health Care Litigation Tracker, Issue: Inflation Reduction Act*, O'NEILL INST. FOR NAT'L & GLOB. HEALTH L. (2023), https://litigationtracker.law.georgetown.edu/issues/inflation-reduction-act/.
[47] Rogers, *supra* note 42, at 17–18 (citing 2019 data that shows U.S. spending double the average average across other OECD countries).
[48] *Id.*
[49] At the time of this paper's drafting, the makers of all 10 of the negotiated drugs have initially committed to participate in the negotiations. The lawsuits remain ongoing. Berkeley Lovelace Jr., *Drugmakers Agree to Negotiate Drug Prices with Government, White House Says*, NBC NEWS (Oct. 3, 2023), https://www.nbcnews.com/health/health-news/medicare-drug-costs-drugmakers-agree-price-negotiations-biden-administ-rcna118510.

II. PRIMARY CONCERNS WITH THE DRUG PRICE NEGOTIATION PROGRAM

A. *Decrease in Research and Development*

The largest concern with the Program is that it will lead to a considerable decrease in pharmaceutical and biotech research and development. There is no debate that the negotiations will save Medicare a remarkable amount of money. But there is strong dispute over how the Program will affect drug development. The CBO estimates that with the IRA in place, there will only be one less drug introduced to the U.S. market between 2023–2032, and five less in the following decade because of the programs effects on research.[50] A competing study organized by the Biotechnology Innovation Organization predicts the effects will be much greater—with a reduction in up to 139 new therapies over the next ten years.[51] The industry report goes on to state that the IRA will have a substantial effect on biopharma revenues, and that it will "primarily impact[] the most successful and innovative therapies, which fund a majority of the R&D in the biopharma ecosystem."[52] The industry invested an average of 28% of revenue towards research in 2022—therefore, a cut in drug revenue directly impacts R&D much more than in other fields, where research is less tied to product sales.[53]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is another vocal opponent of the Program and stresses the unintended consequences. PhRMA quotes member surveys which found that many drugmakers are reconsidering R&D efforts, with 78% expecting to cancel early-state pipeline projects, 63% expecting to shift research away from small-molecule drugs, and 95% expecting to develop less new uses for approved drugs.[54] PhRMA emphasizes that the short period of exclusivity before negotiations ignores the amount of research following a drug's approval and "discourages researchers from following promising scientific leads."[55] Publicly traded pharmaceutical companies have an obvious economic incentive to fight decreases to their bottom line, and there is understandable hesitation to listen to the concerns of an industry with over $200 billion in yearly revenue.[56] This is coupled with the reality that early-stage research is already supported by significant public funding.[57] But the mean cost to develop a modern drug from discovery to launch was $2.5 billion in 2020.[58] And even with generous

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[50] CONG. BUDGET OFFICE, SUMMARY, ESTIMATED BUDGET EFFECTS OF PUBLIC LAW 117-169 15 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

[51] DANIEL GASSULL ET AL., VITALTRANSFORMATION, IRA'S IMPACT ON THE US BIOPHARMA ECOSYSTEM 16 (June 1, 2023), https://vitaltransformation.com/wp-content/uploads/2023/10/VT-BIO_IRA_v14.pdf.

[52] *Id.* at 9.

[53] *Id.* at 11.

[54] Nicole Longo, *WTAS: Inflation Reduction Act Already Impacting R&D Decisions*, PhRMA (Jan. 17, 2023), https://phrma.org/blog/wtas-inflation-reduction-act-already-impacting-rd-decisions.

[55] *Inflation Reduction Act's Unintended Consequences*, PhRMA (2023), https://phrma.org/en/Inflation-Reduction-Act.

[56] IBISWORLD, INDUSTRY REPORT 32541A: BRAND NAME PHARMACEUTICAL MANUFACTURING IN THE U.S. (Nov. 2023).

[57] Study finds that NIH contributed to 99.4% of drugs approved by the FDA from 2010 to 2019 with hundreds of millions of dollars in basic and applied research on drug targets. Ekaterina Galkina Cleary et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, JAMA HEALTH FORUM (Apr. 28, 3023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamahealthforum.2023.0511.

[58] Matej Mikulic, *Average R&D Cost to Develop a Pharmaceutical Compound from Discovery to Launch from 2010 to 2020, by Study Cohort*, STATISTA (Nov. 7, 2022), https://www-statista-com.utk.idm.oclc.org/statistics/825727/randd-cost-for-new-pharma-compounds-by-cohort/.

government support, a large amount of research is sustained by pharmaceutical profits in the United States.

B. *Impact to Global Drug Development*

While the Program may not hit the worst outcome posited by industry reports, a decrease in drug research will have a massive global impact. The United States is the world largest pharmaceuticals market, with a 42% market share in 2022.[59] Then next largest, China, only has a 7.6% market share.[60] Likewise, the U.S. has nearly double the pharmaceutical sales of the next market (all emerging markets) and triple that of Europe.[61] This domination is also seen in drug research. Two-thirds of all research and development spending within the Organisation for Economic Co-operation and Development (OECD) comes from the United States.[62] And in 2022, there were over 10,000 drugs in U.S.-based pipelines, more than double both the EU and China, and four times more than in the United Kingdom.[63]

With the world's focus on U.S. drug development, the FDA has become a de-facto gatekeeper of new drugs, with U.S. approval opening doors for drugs in other countries around the world.[64] Using the massive profit potential and infrastructure for development and approval, drugmakers worldwide rely on the U.S. as a hotbed for innovation and drug research. If this profit potential is limited, research—which is so closely tied to these profits, will diminish. Because no other nation or region comes close to the global impact of U.S. drug research, the uncertainty and risk brought by the Program will affect the worldwide market, unless that risk is absorbed, or another location takes the helm of drug research. And either of those corrections would take considerable time to establish. In the meantime, multiple important new drugs and biologics would be lost.

C. *Disproportionate Effects of Decreased Research*

The other major risk brought by the Program is that negotiations only encompass high-spend drugs that treat a small number of conditions seen by Medicare beneficiaries. From the initial drugs selected for negotiation: five treat cardiovascular disease, four treat diabetes, and two treat psoriasis.[65] The Program's focus on specific indications will push direct investment away from those areas—especially if the Program continues slowly and provides minimal information regarding selection to drugmakers. [66] PhRMA's survey indicates that 82% of pipeline projects in areas that include cardiovascular disease and cancer expect to see substantial impacts on R&D

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[59] Matej Mikulic, Market Share of the Leading Global Pharmaceutical Markets 2022, STATISTA (Aug. 29, 2023), https://www-statista-com.utk.idm.oclc.org/statistics/245473/market-share-of-the-leading-10-global-pharmaceutical-markets/. The OECD is a group of 38 member-states with a majority being high-income, developed economies throughout North and South America, East Asia, and Oceania.

[60] *Id.*

[61] Matej Mikulic, *World Pharmaceutical Sales 2022-2022 by Region*, STATISTA (Sept. 12, 2023), https://www-statista-com.utk.idm.oclc.org/statistics/272181/world-pharmaceutical-sales-by-region/.

[62] Brooke Masters, *The World Will Need to Stop Piggybacking on US Pharma*, FIN. TIMES (Sept. 1, 2023), https://www.ft.com/content/0c20c518-60a8-4dd0-87be-f03adc8ec0e1.

[63] *Id.*

[64] *See* Robin Forrest, *The Size of the US Pharmaceutical Market Means That the US Food and Drug Administration Has a Disproportionately Large Global Influence*, LONDON SCH. OF ECON. BLOGS (Jan. 19, 2023), https://blogs.lse.ac.uk/usappblog/2023/01/19/the-size-of-the-us-pharmaceutical-market-means-that-the-us-food-and-drug-administration-has-a-disproportionately-large-global-influence/.

[65] SELECTED DRUGS, *supra* note 4.

[66] For a discussion on if Medicare beneficiaries are representative of the general population's drug needs, s*ee* discussion *infra* Part IV.

decisions due to the Program.[67] Other industry experts expect research cuts for "diseases of aging" that include Alzheimer's, osteoporosis, and cancer.[68]

These diseases affect millions of Americans and drug costs for their treatment deserve attention. Over eight million Medicare beneficiaries alone took one of the five selected drugs that treats cardiovascular disease (CVD).[69] But CVD drug development has diminished in recent years.[70] A case study reviewed how the IRA may affect development timelines in CVD development pipelines. It found large study enrollments and the use of small molecules, which are eligible to negotiate earlier than biologics, presented fewer options to recoup investments on subsequent post-approval indications if the drugs entered negotiations.[71] If these additional indications are deprioritized, millions of patients lose out on potential treatment options.[72] As stated earlier, the extent of industry research downturn has yet to be confirmed. During the initial stages of negotiations, and in the midst of ongoing litigation, drugmakers will appeal to the public and the worst-case scenario. But the industry still faces verified impacts from multiple risks and economic trends.[73] This added and ongoing yearly possibility of price negotiations will be absorbed by the industry and must be accounted for.

III. MEDICARE AS A NEGOTIATION PLATFORM

Beyond the concerns voiced on the Program's effects on research and development, there is an overarching question: is Medicare is the best platform to negotiate prescription drug pricing nationwide? At face level, these negotiations would appear to be a natural progression of Medicare's strategic direction to "achieve[] equitable outcomes through high quality, affordable, person-centered care."[74] It also seems practical from a statutory perspective, as Medicare's national reach is based in federal law, while the private insurance market is fragmented among payers.[75] However, there is reason to doubt that the Medicare population is representative of the U.S. population as a whole. And by focusing on the primary medical needs of Plan B and D beneficiaries, other groups will be negatively affected.

Of the nearly 63 million Medicare beneficiaries in 2019, 74% were enrolled in Part D prescription coverage, and 62% were enrolled in Parts A or B.[76] A vast majority of Medicare beneficiaries, 86.2%, received eligibility from being age 65 or older, and 76.0% were White (Non-

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[67] *Health Care Policy Should Get Us Closer to Health Equity. The Inflation Reduction Act Fails To Do* So, PHRMA, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/IRA-Equity-1-pager_cited.pdf.

[68] Letter from Peter Kolchinsky et al., to President Joseph Biden et al. (Sept. 8, 2021), https://nopatientleftbehind.docsend.com/view/a6bxibzxysaeggm3.

[69] MILENA SULLIVAN ET AL., AVALERE, IRA DRUG PRICE NEGOTIATION IMPACT ON CARDIOVASCULAR DRUGS 2 (2023); *see* SELECTED DRUGS, *supra* note 4.

[70] *Id.*

[71] *Id.* at 3.

[72] *Id.*

[73] Hillary Dukart et al. *Emerging From Disruption: The Future of Pharma Operations Strategy*, MCKINSEY & CO. (Oct. 10, 2022), https://www.mckinsey.com/capabilities/operations/our-insights/emerging-from-disruption-the-future-of-pharma-operations-strategy.

[74] *Strategic Direction*, CTRS. FOR MEDICARE & MEDICAID SERVS. (2023), https://www.cms.gov/priorities/innovation/about/strategic-direction.

[75] *See* 42 U.S.C. § 1395j (establishing supplemental medical insurance program for the aged and disabled); The McCarran-Ferguson Act of 1945, 15 U.S.C. §§ 1011-1015.

[76] WAFA TARAZI ET AL, OFFICE OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUM. SERV., MEDICARE BENEFICIARY ENROLLMENT TRENDS AND DEMOGRAPHIC CHARACTERISTICS 1 (Mar. 2, 2022), https://aspe.hhs.gov/sites/default/files/documents/f81aafbba0b331c71c6e8bc66512e25d/medicare-beneficiary-enrollment-ib.pdf.

Latino).[77] Additionally, 52.1% of the 2019 beneficiaries attended college, and 14.0% had less than a high school education, but Part A only beneficiaries had a much higher education level (71% attended college) than Part B (only 13.3%).[78] Of total beneficiaries, 59.1% had an income of greater than two-hundred times the Federal Poverty Level (FPL).[79] But those enrolled only in Part B were "more likely to be dually enrolled [in Medicare and Medicaid], have lower incomes, and have health conditions . . . compared to all Medicare beneficiaries."[80] Part C Medicare Advantage (MA) beneficiaries were also more likely than those with traditional Parts A and B coverage to report incomes below 100% of the FPL, be older than 74, and have less education.[81]

Overall, the beneficiary trends point to a group who is disproportionately White and older than the U.S. population.[82] This same group also has lower incomes and levels of education than the U.S. average, but these differences are not spread equally amongst the beneficiaries.[83] MA enrollees have lower income and education levels than traditional Parts A and B beneficiaries, and Part B-only recipients have much lower education and income rates amongst all groups.[84] The report further described how the 5.7 million beneficiaries without any drug coverage were "more likely to have lower incomes, have less than a college degree, . . . and have multiple health conditions, compared to beneficiaries with private drug coverage."[85] So not even all those on Medicare will reap the Program's benefits—including those most in need of them.

The 2023 Medicare beneficiary data also demonstrates that the patient population is subject to a cluster of chronic health conditions. Of total fee-for-service beneficiaries, 56% had chronic high blood pressure, 50% had high cholesterol, 33% had arthritis, and 26% had diabetes and/or heart disease.[86] Several of these conditions are listed within the United States' leading causes of death, but they are also generally indicative of the symptoms of an aging population.[87] It is clear these indications affect tens of millions and require a significant amount of care. But the Program's singular focus on these conditions ignores other major health issues—including acute trauma care—that affect younger or underrepresented communities at much higher rates.[88] Lowering some drug costs for a primarily elderly beneficiary group fails to lower the price of any non-negotiated drug and does nothing to otherwise expand access to these medications.

A recent study indicates that "public health intervention to prevent the onset of chronic conditions in early life may be needed to eliminate [] disparities" of multimorbidity in in the Black

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[77] *Id.* at 6.
[78] *Id.*
[79] *Id.*
[80] *Id.* at 5.
[81] *Id.*
[82] *Id.* at 11.
[83] *Id.*
[84] *Id.*
[85] 13.4% of beneficiaries have private drug coverage, and 84% of all Medicare beneficiaries have some form of supplemental coverage. *Id.* at 1.
[86] *2023 Edition: Medicare Beneficiaries At a Glance*, CTRS. FOR MEDICARE & MEDICAID SERV. (2023), https://data.cms.gov/infographic/medicare-beneficiaries-at-a-glance.
[87] *Leading Causes of Death*, NAT'L CTR. FOR HEALTH STATS., CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm (noting heart disease as leading cause of death and listing of diabetes as eighth leading cause); *see The Top 10 Most Common Chronic Conditions in Older Adults*, NAT'L COUNCIL ON AGING (Aug. 31, 2023), https://www.ncoa.org/article/the-top-10-most-common-chronic-conditions-in-older-adults (providing a list that nearly mirrors the Medicare chronic condition list).
[88] *Leading Causes of Death*, NAT'L CTR. FOR HEALTH STATS., CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm (listing accidents or "unintentional injuries" as the cause of 224,935 deaths in the United States); *see Black/African American Health*, OFFICE OF MINORITY HEALTH, https://minorityhealth.hhs.gov/blackafrican-american-health ("The death rate for Blacks/African Americans is generally higher than whites for COVID-19, . . . HIV/AIDS, and homicide.").

population.[89] Another found that children have been disproportionately affected by racial and ethnic health disparities in chronic disease prevention and treatment.[90] If the Program results in higher drug prices or fewer treatment options, efforts to increase access to care and erase healthcare disparities in underserved communities will continue to struggle. Drug pricing is only a small piece of what is needed to address these issues, but it is a significant one.[91] This is also considerably important in combatting childhood health inequality, because minority groups and uninsured children currently receive a small fraction of the prescription drugs given to nonminority and insured children.[92]

Instead of focusing solely on the medical expenses of Medicare beneficiaries, the federal government should look to the needs of a broader population with particular attention paid to underserved and marginalized communities. The chronic conditions treated by the Program's initial list of drugs are prevalent in these underserved groups.[93] And while there is no consensus that lower Medicare drug prices will transfer to private insurance, these communities will not see any potential savings because they suffer from much lower rates of insurance coverage.[94] Another impact these communities face is drug availability. Decreases in research and development already affect diseases that "disproportionately impact historically underserved populations," and the trend will continue under the Program.[95] But this does not mean that the Program should abruptly end. Rather, HHS should not presume that success in lowering drug prices for Medicare recipients will automatically create lower drug prices for groups who desperately need these cost savings. The government should instead focus on a holistic, nation-wide approach to balance the needs of an aging population with acute and preventative care for younger and more diverse groups.

IV. PROPOSED SOLUTIONS

The Medicare Drug Price Negotiation Program should not continue in its currently form, and it cannot be relied upon to provide lower prescription drug costs to all Americans. This two-part proposal first discusses a pathway to improve the negotiation program and then provides a second, overarching directive that Congress must directly attack the cost of drugs within the private market.

A. *Rapid Expansion of the Medicare Negotiation Program*

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[89] Cesar Caraballo et al, *Temporal Trends in Racial and Ethnic Disparities in Multimorbidity Prevalence in the United States, 1999-2018*, 135 AM. J. MEDICINE, No. 9, 1083, 1083 (2022).

[90] James H. Price et al., *Racial/Ethnic Disparities in Chronic Diseases of Youths and Access to Health Care in the United States*, BIOMED RSCH. INT'L 1 (Sept. 23, 2013).

[91] *Id.* at 8.

[92] *Id.*

[93] Eliquis is used to prevent and treat blood clots, while Jardiance is prescribed for diabetes and heart failure. *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Aug. 2023); *Black/African American Health*, OFFICE OF MINORITY HEALTH, , https://minorityhealth.hhs.gov/blackafrican-american-health ("The death rate for Blacks/African Americans is generally higher than Whites for COVID-19, heart disease, stroke, cancer, asthma, influenza and pneumonia, diabetes, HIV/AIDS, and homicide.").

[94] *See* James H. Price et al., *Racial/Ethnic Disparities in Chronic Diseases of Youths and Access to Health Care in the United States*, BIOMED RSCH. INT'L 8 (Sept. 23, 2013).

[95] *Health Care Policy Should Get Us Closer to Health Care Equity. The Inflation Reduction Act Fails To Do So*, PHRMA, https://phrma.org/en/resource-center/Topics/Equity/Health-care-policy-should-get-us-closer-to-health-equity---The-Inflation-Reduction-Act-fails-to-do-so.

The Program should rapidly expand and require that all eligible drugs across Medicare Plans B and D have a negotiated price. This approach will drastically reduce the program's ongoing risk and uncertainty as all drugmakers immediately become aware that they will negotiate. A rapid expansion will cause an initial shock to the market, but the resulting decrease in uncertainty quickly assuages industry fears and is more conducive to mid- and long-term drug research and development.

In the revised guidance on the Program, CMS responded to requests for greater transparency into the drug selection process.[96] CMS stated that they are statutorily required to identify negotiation-eligible drugs using total Medicare expenditure calculated from Prescription Drug Event (PDE) data.[97] Further requests that manufacturers receive notification prior to the statutory deadline of September 1, 2023, were deemed impossible to meet due to the complexity of analyzing the data.[98] The revised guidance disclaims that the Program's drug selection is mandated, as the statute requires "CMS [to] select the ten negotiation-eligible drugs with the highest Total Expenditures under Part D of Title XVIII for negotiations for initial price applicability year 2026 . . . and [then] publish a list of those ten selected drugs . . . ."[99] The Act's requirements for drug selection are publicly available, but Medicare's expenditure information—which is used to determine those drugs—is not released.

PDE records used in the selection process remain complex and guarded. They "contain prescription drug cost and cost payment data that enables CMS to make payments to plans and otherwise administer the Part D benefit."[100] Full PDE data is only available for research purposes.[101] Research is defined per HIPAA, as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[102] Identifiable data used for commercial purposes is not released.[103] Companies looking to research PDE records, to determine whether their products could be included in upcoming negotiations, would likely be barred from using this channel as it falls outside the scope of HIPAA's definition of research and enters commercial activity. While limited data sets can be requested and used commercially, they lack the full amount of information needed to accurately project negotiation eligibility. [104] The Program's selection process seems clear at a high level, but quickly becomes opaque.

Drugmakers are dependent upon CMS to publicly announce the negotiations, and under the current process, they must hold their breath on a yearly basis. And they will continue to do so because only a small number of drugs are selected each year.[105] The incredibly slow trickle of negotiations from a pool of more than 3,500 drugs covered under Plan D is by design, as only a few drugs make up a substantial portion of Medicare spending.[106] The top ten selling drugs

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[96] CMS REVISED GUIDANCE, *supra* note 29.
[97] *Id.*
[98] *Id.* at 21.
[99] *Id.* at 98.; Inflation Reduction Act of 2022, Pub. L. 117-169, § 1192(a) (2022).
[100] *Questions and Answers on Obtaining PDE Data*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1, https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-claims-data (select PDF from "Downloads").
[101] *Id.*
[102] *Id.*
[103] *Id.*
[104] *See id.*
[105] Juliette Cubanski, *FAQs About the Inflation Reduction Act's Medicare Drug Price Negotiation Program*, KFF (Aug. 8, 2023), https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/ (stating 10 drugs selected in 2026, 15 selected in 2027 and 2028, and 20 in 2029 and thereafter).
[106] Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, KFF (Jul. 12, 2023), https://www.kff.org/medicare/issue-brief/a-small-number-of-drugs-account-for-a-large-share-of-medicare-part-d-spending/.

accounted for 22% of total gross Part D spending in 2021.[107] Expanding the list, the top 50 drugs accounted for 47% of total gross spending, or $67.3 billion out of the $215.7 billion in gross spending.[108] The Program will achieve the goal of "lower[ing] health care and prescription drug costs and ushering in a new era for American seniors" by negotiating down these highest spending drugs.[109] But the statute provides no finish line or end date.[110] After the costliest medications are tackled, the Program marches on with 20 negotiations per year. If the purpose was to simply "trim the fat," then a statutory end date for the negotiations would be set. However, the drafters of the Act set the Program to continue indefinitely.[111]

As discussed in Part III, government and industry analysts disagree on the long-term effects that Medicare price negotiations will have on drug development. [112] Since the IRA became law in August 2022, its economic impact on the pharmaceutical industry has been muted. One article analyzing M&A investment activity before and after the IRA was instituted found "little evidence suggesting a disruption in activities and investments that will yield new pharmaceutical products," and concluded "the investment environment for drug development remains largely unchanged by the IRA's drug price negotiation program and is not currently threatened by it."[113] Other analysts are less certain and note that "the new law is affecting capital allocation based on the types of M&A transactions announced and shifting R&D focus." [114]

It is impossible to predict the long-term impact of the Program, but industry leaders have plainly stated that decisions on pipeline development are based on current legislative language.[115] And those leaders are already considering cutting programs—including cancers that often affect the elderly—due to concerns about investment returns before they are potentially required to negotiate with CMS.[116] Much of this language could be industry bluster and fearmongering in the Program's infancy, but the vocalized worry is noted by investors, especially as industry financials become directly impacted by the Program for the first time.[117]

If the program continues with only twenty negotiations per year, and drugmakers cannot accurately predict their inclusion on negotiation list, internal development will shy away from this risk, and companies will be less likely to invest internally and in smaller startups that

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[107] *Id.*
[108] *Id.*
[109] *Fact Sheet: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation*, WHITE HOUSE (Aug. 29, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/.
[110] 42 U.S.C. § 1320f-1(a)(4) (describing selection of negotiation-eligible drugs for initial price applicability year 2029 "or a subsequent year").
[111] *Fact Sheet: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation*, *supra* note 109 ("Medicare will negotiate prices for up to 60 drugs covered under Medicare Part D and B, and up to an additional 20 drugs every year after that.").
[112] *See* CONG. BUDGET OFFICE, *supra* note 50; GASSULL ET AL., *supra* note 51, at 9.
[113] Richard G. Frank & Ro W. Huang, *Early Claims and M&A Behavior Following Enactment of the Drug Provisions in the IRA*, BROOKINGS (Aug. 23, 2023), https://www.brookings.edu/articles/early-claims-and-ma-behavior-following-enactment-of-the-drug-provisions-in-the-ira/.
[114] Fitch Wire, *US IRA May Weigh on Long-Term Global Pharma Growth*, FITCH RATINGS (Sep. 22, 202 3), https://www.fitchratings.com/research/corporate-finance/us-ira-may-weigh-on-long-term-global-pharma-growth-22-09-2023.
[115] Hannah Kuchler & Jamie Smyth, *Novartis Boss Warns US Drug Pricing Reform Poses Risk to Public Health*, FIN. TIMES (July 25, 2023), https://www.ft.com/content/46584130-85df-4e63-b197-3ea26bab6809.
[116] *Id.*
[117] *See Half of Top 20 Biopharma Company Market Cap Impacted Amid the IRA in Q3 2023*, PHARMACEUTICAL TECHNOLOGY (Oct. 31, 2023), https://www.pharmaceutical-technology.com/analyst-comment/half-of-top-20-biopharma-ira-q3-2023/?cf-view&cf-closed (Flagging Johnson & Jonson's 12.2% capitalization decline largely attributed to its inclusion in the Program).

currently serve as a major incubator of drug development.[118] But if the Program is quickly expanded, drugmakers are put on notice that their products on Plan D and Plan B formularies will soon be negotiated and the risk bubble is popped. The market will be forced to incorporate these costs into their financial modeling, and while there will be considerable frustration at the onset, the outcome will equalize as parties realize significant profits can still be made.[119] Concern that a sizable number of pharmaceutical companies will drop from Medicare when the Plan D enrollee count totals 46.5 million Americans is negligible—the market is just too large.[120] Growing pains should not influence the expansion of the negotiations because they are unavoidable. Even in the current Program, drugmakers have made clear their desire to litigate.[121] The overall risks to medical research and development found in the current Program are unlikely to significantly change in this rapid expansion model as the negotiation format and penalties are not altered. And overall, the uncertainty of an expanded Program will decrease quickly once drug negotiation timelines are released.[122] It would also serve to diminish the confusion around the selection process and use of PDE data as the negotiation pool would be much larger.[123]

An expansion of the Drug Price Negotiation Program is not without its criticism. Primarily, this does not change the Program, it simply broadens its scope and hastens its effects.[124] Industry concerns of decreased research and investment are not diminished. By requiring a greater number of companies to negotiate earlier and in a shorter amount of time, the predicted decreases in investment and research would likely intensify for the short term.[125] Legal challenges to the Program would likewise continue and may increase in scope when more drugmakers are brought to the negotiation table.[126] The Program's expansion would also require a new or amended law. Plan D's noninterference provision remains in effect, and the Program only exists as a statutory exception.[127] As such, the number of negotiated drugs is set by law.[128] To raise the number of drug negotiations beyond the twenty per year in 2029 and later, the Act would need to be amended. And in today's political climate, that prospect is shaky at best.[129] Yet while these implementation

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[118] This is especially true in the small-molecule space, where fear over unrealized investment returns is already influencing funding decisions. *America's Plan to Cut Drug Prices Comes With Unpleasant Side-Effects*, THE ECONOMIST (Aug. 29, 2023), https://www.economist.com/business/2023/08/29/americas-plan-to-cut-drug-prices-comes-with-unpleasant-side-effects [hereinafter *Unpleasant Side-Effects*].

[119] Additional government funding could be used to soften the impact of these negotiations. NIH contributions applied towards basic and initial drug research could be expanded into clinical trial grants or other means to encourage development of drugs likely to be negotiated upon by CMS. *See* Cleary et al., *supra* note 57.

[120] Wafa Tarazi et al, *Medicare Beneficiary Enrollment Trends and Demographic Characteristics*, OFFICE OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUM. SERV. 9 (Mar. 2, 2022).

[121] *See* Lauren Gardner, *Drugmakers, Trade Groups Push Back Against Medicare Drug Price Negotiations*, POLITICO (Aug, 29, 2023), https://www.politico.com/news/2023/08/29/drugmakers-trade-groups-push-back-against-medicare-drug-price-negotiations-00111936.

[122] The suggested expansion would utilize the current Program's requirements for 7 years of market availability for small drugs and 11 years for biologics. However, industry concerns related to the "small-molecule penalty" for the lower exclusivity period for small-molecule drugs must be considered. *See Unpleasant Side-Effects*, *supra* note 118.

[123] *See* CMS REVISED GUIDANCE, *supra* note 29.

[124] For brevity, a specific recommendation on the number of drug negotiations per year is not provided. Separate analysis would be needed.

[125] *See Inflation Reduction Act's Unintended Consequences*, *supra* note 55.

[126] *See generally* HANNAH-ALISE ROGERS, CONG. RSCH. SERV., R47682, CONSTITUTIONAL CHALLENGES TO THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM (2023) (discussing the multiple constitutional challenges to the Program and suggested considerations).

[127] 42 U.S.C. § 1395w-111(i) (defining the noninterference provision); § 42 U.S.C. § 1320f (establishing the Program).

[128] 42 U.S.C. § 1320f-1(a)(4).

[129] *See Medicare Part D: The Noninterference Clause*, S. REPUBLICAN POL'Y COMM. (May 22, 2019) (discussing party apprehension on government drug negotiations), https://www.rpc.senate.gov/policy-papers/medicare-part-d-the-noninterference-clause.

obstacles are relevant, the decrease in uncertainty and risk caused by the Program's expansion, coupled with beneficiary savings, make this proposal worthwhile.

B. *Look Beyond Medicare: Focus on Private Insurance to Control Drug Costs*

The proposal above is designed to improve the Program in its current form. It does not address that the Program itself cannot act as a panacea for the high cost of prescription drugs across the U.S. healthcare system. The Program will lower drug prices for Medicare and its beneficiaries. But those lower prices will not be seen by those under private insurance or who lack health insurance in the first place.[130] The Biden Administration hails the effort as a "major step towards lower health care costs for seniors and families."[131] And that precisely what it is—an effort toward lowering costs for seniors on Medicare. The Program's focus on the elderly population and their primary pharmaceutical concerns may even come at the expense of other groups.[132] To truly decrease drug costs for the greater population, efforts must focus on private health insurance.

In 2022, 92.1% of Americans had some form of health insurance.[133] Of this group, 54.5% had employer-based insurance, 18.7% received insurance through Medicare, and 18.8% were enrolled in Medicaid.[134] Further, 7.9% of the population was uninsured.[135] Accordingly, 73% of insured Americans will not be directly affected by the Medicare negotiations or the resulting price caps.[136] A debate remains if drug price negotiations will result in direct cost-shifting to private plans.[137] But even if the Program does not raise the prices of non-negotiated drugs, the majority who rely on employer-based or non-Medicare insurance options will not see their costs decrease.[138] The Program cannot negotiate prices for anyone outside of Medicare. And its beneficiary population is already skewed from the general demographics and health needs of all Americans.[139] If the true policy goals are to lower prescription drug prices for all rather than just decrease spending, the government must enact legislation that targets consumer drug costs within private insurance plans.

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[130] Robert King & David Lim, *Will Drug Price Negotiations Work? Here's What You Need to Know*, POLITICO (Aug. 28, 2023) https://www.politico.com/news/2023/08/28/what-to-know-medicare-drug-price-negotiations-00113081#.

[131] *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program*, WHITE HOUSE (Oct. 3, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/03/biden-harris-administration-takes-major-step-forward-in-lowering-health-care-costs-announces-manufacturers-participating-in-drug-price-negotiation-program/.

[132] *See* discussion *supra* Part IV.

[133] KATHERINE KEISLER-STARKEY ET AL., U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2022 3 (Sept. 2023), https://www.census.gov/content/dam/Census/library/publications/2023/demo/p60-281.pdf.

[134] *Id.*

[135] *Id.*

[136] *See id.*

[137] *See* Loren Adler, *Cost-Shifting in Drug Pricing, or the Lack Thereof*, BROOKINGS (Sept. 24, 2021), https://www.brookings.edu/articles/cost-shifting-in-drug-pricing-or-the-lack-thereof/ (arguing that negotiations near and long-term effects; Rena M. Conti et al., *How Do Commercial Insurance Plans Fare Under Proposed Prescription Drug Price Regulation?*, JAMA HEALTH FORUM (Dec. 23, 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2787467 (providing two reasons why drugmakers may respond to Medicare price regulation by raising drug prices in commercial plans).

[138] *See e.g.*, Tami Luhby, *Senate Drug Price Bill is Limited to Medicare. Here's What it Means for Those With Private Insurance*, CNN (Aug. 9, 2022), https://www.cnn.com/2022/08/09/politics/senate-medicare-drug-cost-bill-private-insurance/index.html (discussing the Program's "little impact on the private market").

[139] *See* TARAZI ET AL., *supra* note 76, at 9 and accompanying text.

There are countless proposals on how the government should act to lower drug costs under private insurance.[140] One suggestion that has grown in popularity, is to regulate Pharmacy Benefit Manager (PBM) transparency and require full passthrough of negotiated drug rebates. PBMs are companies who manage prescription benefits on behalf of other parties—including insurers, Medicare Part D plans, and employers.[141] They negotiate directly with drugmakers and pharmacies, and have a significant determination in the drug costs for insurers.[142] PBMs operate in the middle of the distribution chain, where they develop insurer formularies, use their large purchasing power to negotiate rebates and discounts from the drugmakers, and even directly contract with pharmacies to reimburse them for the drugs dispensed to beneficiaries.[143]

PBMs and their private negotiations with drugmakers are often cited as one of the reasons why prescription drug costs have skyrocketed for many Americans.[144] The power that PBMs hold in setting prices and receiving discounts is immense, especially when a small handful of companies manage nearly all prescription claims in the United States.[145] In fact, three companies control 80% of the prescription claims market, and six control 96%.[146] PBMs have come under the public spotlight, and as of October 2023, there are at least four PBM reform bills introduced in Congress.[147] One bill for example, would mandate that PBMs pass along 100% of the negotiated rebates and fees to the insurance plan sponsor.[148] Requiring rebate passthrough, or mandating disclosure of these rebate amounts is legislation that directly attacks the cost of drugs, and should be encouraged. But it is certainly not without risk or criticism.

Any legislation of this type is fraught with legal and economic challenge. There are preliminary questions on if drug price legislation should be focused at a state or national level—especially as proactive state-based laws are held up by multiple administrative barriers and regulatory clogs.[149] Federal bills also face heightened constitutional and political scrutiny when they move beyond Medicare and directly interfere with business negotiations between private parties.[150] And when a bill targets specific aspects of the healthcare system to lower costs, there

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[140] *See e.g.*, Haley Gintis, *A Prescription for America's Prescriptions*, 35 EMORY INT'L L. REV. 63 (2021).

[141] *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019) https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending.

[142] *Id.*

[143] *Id.*

[144] *See e.g.*, *High Drug Prices: Are PBMs the Right Target?*, BIPARTISAN POL'Y CTR. (Feb. 2, 2023) (noting the increased scrutiny of PBMs and healthcare prices), https://bipartisanpolicy.org/blog/are-pbms-the-right-target/.

[145] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2022: Market Share and Trends for the Biggest Companies*, DRUG CHANNELS (May 23, 2023), https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html.

[146] *Id.*

[147] Christopher Cai & Benjamin N. Rome, *Reforming Pharmacy Benefit Managers – A Review of Bipartisan Legislation*, 389 NEW ENG. J. MED. 1640, 1641 (2023).

[148] A major point of PBM criticism is that they often keep a portion of the rebates received from negotiations with the manufacturers. Therefore, requiring them to pass the entire amount of rebate savings to the plan sponsor is a part of multiple bills and proposals. It is also important to note that these proposals require rebate passthrough to the plan providers but not to the patients themselves as aiming for more aggressive reforms is currently seen as "politically and economically challenging." *Id*. *See Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending (discussing that proposals to regulate PBMs include: require greater rebate transparency, ban spread pricing, and require PBMs to pass through rebates to payers or patients).

[149] Buck, *supra* note 6, at 202 (noting ERISA, Dormant Commerce Clause, Medicaid Waiver Requests, and Patent Law as primary barriers to effective state-level action in prescription drug price regulation).

[150] Actions of Congress in this area could be defendable under their expansive power to regulate interstate commerce. *See e.g.*, *Wickard v. Filburn*, 317 U.S. 111 (1942) (holding private production can be regulated if it exerts a substantial

are questions on if that is the appropriate target,[151] or if unforeseen repercussions will defeat the legislation's purpose.[152] This paper cannot defend or validate all current attempts to normalize private market drug prices. Even the highlighted suggestion towards PBM legislation requires extensive analysis. Rather, it is critical to understood that the government *must* do more to fight prescription drug prices, and these actions should take aim at the private insurance that most Americans rely upon.[153] The Medicare Drug Price Negotiation Program cannot be the endgame. Nor can it be relied upon to give all Americans relief from rising drug prices. Even if the proposal within this Part V of the paper is utilized, more must be done, and it must be done soon.

CONCLUSION

The current form of the Medicare Drug Price Negotiation Program will cause continuous industry uncertainty and result in a decrease of research for promising new drugs. To lessen risk and mitigate this uncertainty, the Program should rapidly expand the number of negotiations beyond its maximum of twenty per year. This will cause an initial market shock, but results in a net decrease of risk over time. And once absorbed by the market, the lower economic risk will translate to stabilized or increased expenditure in drug research. In addition, the negotiation program should not be seen as a method to decrease prescription drug prices outside of Medicare. The government must work to create beneficial legislation that targets drugs costs under private insurance. Until that happens, a vast majority of Americans will not see relief from unaffordable drugs and medications.

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economic effect on interstate commerce). But that ability weighs against the significant political and economic interests of drugmakers and insurance providers.

[151] *High Drug Prices: Are PBMs the Right Target?*, *supra* note 144.

[152] Rebecca Pifer, *PBM Reforms in Congress Would Have Modest Effect at Best and Backfire at Worst, Brookings Says*, HEALTHCARE DIVE (Sept. 13, 2023), https://www.healthcaredive.com/news/pbm-congress-legislation-drug-prices-spending-modest-effect-brookings-institute/693181/.

[153] KEISLER-STARKEY ET AL., *supra* note 133, at 3.