MEDICARE'S MAKING OF A MONSTER: HOW THE U.S. MEDICARE PROGRAM INADVERTENTLY CONTRIBUTES TO BARRIERS TO ACCESS IN THE PRESCRIPTION DRUG MARKET

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"I ought to be thy Adam, but I am rather the fallen angel . . . ."
—Mary Shelley, Frankenstein[1]

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1. Mary Shelley, FRANKENSTEIN OR THE MODERN PROMETHEUS 96 (Knopf ed., 1992).

The U.S. Medicare program plays a pivotal role in this country's healthcare delivery system.[2] *Medicare's public insurance program, which is designed for the elderly and certain persons with long-term disabilities,*[3] *has long shouldered responsibility for the medical care of many of the nation's most infirm and vulnerable. While Medicare is undoubtably a necessary component of the current U.S. healthcare system, critical flaws in the program's design have contributed to a growing number of ills. Medicare policy choices have unintentionally created a "monster," which both contributes to rapidly escalating prescription drug costs and discourages pharmaceutical innovation in the areas where it is most urgently needed. The recently-enacted Inflation Reduction Act ("IRA")*[4] *contains provisions which purportedly allow Medicare to "negotiate" prices for certain medications and require manufacturers to pay "rebates" if the prices for specific drugs increase more than the rate of inflation. The statute, however, was significantly watered-down during drafting to ensure its passage. As a result, the bill that was ultimately enacted is lacking in both bite and scope, being not only limited in applicability to a small subset of prescription drugs but also riddled with regulatory loopholes. These shortcomings leave this most recent attempt at Medicare reform susceptible to manipulation by a variety of industry participants, participants which operate within a complex and often-opaque system of payment and reimbursement.*

Importantly, Medicare's policy choices have rippling effects on the broader market for prescription drugs. Here, features of Medicare's drug program contribute to the barriers to access experienced by both Medicare and non-Medicare populations.[5] *Notwithstanding, notably scant attention has been afforded to the wider implications of Medicare design on healthcare access. The complexity of factors influencing the pharmaceutical industry enables these secondary consequences of Medicare policy choices to be easily ignored despite the outsized significance of the program's influence.*

2. Medicare was created under the Social Security Act of 1965, Pub. L. No. 89-97, 79 Stat. 286, and originally was administered by the Department of Health, Education and Welfare. After the agency's reorganization during the 1980s, the Centers for Medicare & Medicaid Services ("CMS") was created to take over the administration of both Medicare and Medicaid, within the Department of Health and Human Services ("HHS"). CMS also is responsible for the administration of the Children's Health Insurance Program ("CHIP"). *See CMS' Program History*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 6, 2023, 4:51 PM), https://www.cms.gov/about-cms/agency-information/history [https://perma.cc/68X6-5M29].

3. Medicare is a federal program that provides health insurance coverage for individuals aged sixty-five and older, as well as for certain people who are under age sixty-five with disabilities and those with end-stage renal disease. *See* S. REP. NO. 116-120, at 2 (2019).

4. Inflation Reduction Act of 2022, Pub. L. No. 117–169, 136 Stat. 1818 (2022) (codified in part at 43 U.S.C. §§ 1302f–1302f-7).

5. *Spending on Prescription Drugs Has Been Growing Exponentially over the Past Few Decades*, PETER G. PETERSON FOUND. (Mar. 26, 2023), https://www.pgpf.org/infographic/spending-on-prescription-drugs-has-been-growing-exponentially-over-the-past-few-decades [https://perma.cc/YT2K-7AQ6].

This Article seeks to inform the development of effective prescription drug pricing reform by parsing the tangled web of Medicare structure and policy and examining the program's impacts on the pharmaceutical industry. To accomplish this goal, it provides an overview of the prescription drug market and examines how it is affected, both directly and indirectly, by Medicare policy. It concludes by proposing the creation of an independent body tasked with coordinated oversight over the pharmaceutical industry.

Introduction

Policymakers continue to grapple with how best to address the rising prices of prescription drugs in the United States, where costs are among the highest in the world.[6] In 1980, average per-person spending on prescription drugs in the U.S. totaled $140 per year.[7] Today, that figure has jumped to $1,073 annually.[8] While legislative measures to reduce the prices paid by the general public for prescription drugs have been proposed,[9] such measures have generally been isolated from the debate over Medicare policy. Conversely, debates regarding changes to the Medicare paradigm typically exclude consideration of how Medicare policy choices might affect the broader prescription drug market. Instead, discussions related to Medicare prescription drug pricing reform tend to be dominated by the voices of politically powerful groups, such as "Big Pharma" and the American Association of Retired Persons ("AARP"),[10] with scant consideration given to how the program's structure and reimbursement policies might affect healthcare access for those not covered by Medicare.[11]

6. Indeed, a recent survey indicates that those in the U.S. are paying twice or even three times as much as those living in other developed countries for their prescription drugs. *See* Katharina Buchholz, *U.S. Drug Prices Sky-High in International Comparison*, STATISTA (Aug. 9, 2022), https://www.statista.com/chart/27932/us-prescription-drug-prices-in-international-comparison [https://perma.cc/KN29-4F4U]; *see also How Does the U.S. Healthcare System Compare to Other Countries?*, PETER G. PETERSON FOUND. (July 12, 2023), https://www.pgpf.org/blog/2023/07/how-does-the-us-healthcare-system-compare-to-other-countries [hereinafter *How Does the U.S. Healthcare System Compare*] [https://perma.cc/TP64-UXGN] (noting that the United States had the highest healthcare spending per capita of any wealthy country in 2021).

7. CONG. BUDGET OFF., PRESCRIPTION DRUGS: SPENDING, USE, AND PRICES 3 (2022), https://www.cbo.gov/publication/57772 [hereinafter CBO, PRESCRIPTION DRUGS] [https://perma.cc/M6LW-LJK7].

8. *Id.*

9. *See, e.g.*, *2024 State Legislation to Lower Prescription Drug Costs*, NAT'L ACAD. FOR ST. HEALTH POL'Y (Mar. 29, 2024), https://nashp.org/state-tracker/2024-state-legislation-to-lower-pharmaceutical-costs/ [https://perma.cc/BN43-3XMD].

10. *See* Michael T. Heaney, *Brokering Health Policy: Coalitions, Parties, and Interest Group Influence*, 31 J. HEALTH POL'Y & L. 887, 890 (2006).

11. *Id.* at 929

Notwithstanding this inattention, Medicare policy exerts significant influence over the broader prescription drug market, impacting not only the profitability of the pharmaceutical industry but also the incentives offered to drive drug innovation. Accordingly, any viable solution to the twin problems of exorbitant prescription drug prices and the need to provide forceful inducements for vital pharmaceutical innovation requires a holistic assessment of this country's pharmaceutical delivery system—one that includes consideration of the impacts of Medicare's drug cost reimbursement structure. Only with a complete picture of the prescription drug landscape can policymakers effectively balance the interests of these often-competing stakeholders.

This Article builds on the work of Daniel J. Hemel and Lisa Ouellette in *Valuing Medical Innovation*[12] and Margaret E. Blume-Kohout and Neeraj Sood in *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*,[13] to explore the fundamental flaws in Medicare design—flaws which have not only undermined the effectiveness of the Medicare system but have also impacted both the cost and type of drugs available to the general public.[14]

The role of Medicare policy is often obscured by the complexity of the U.S. healthcare system and the influence of a vocal set of interest groups dominating discussions of Medicare reform. This Article attempts to help unravel the convoluted system of incentives operating within the prescription drug market by specifically analyzing the influence of Medicare policy on the pharmaceutical industry's pricing and investment decisions. Organization is as follows:

Part I provides an overview of the prescription drug market and the major challenges of enacting effective reform within the current political and regulatory landscape in the United States. Notably, reform will require the resolution of difficult policy questions, such as determining what constitutes a "fair price" for a particular drug.

12. Daniel J. Hemel & Lisa Larrimore Ouellette, *Valuing Medical Innovation*, 75 STAN. L. REV. 517 (2023) [hereinafter Hemel & Ouellette, *Valuing Medical Innovation*].

13. Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. PUB. ECON. 327 (2013).

14. *See* Juliette Cubanski & Tricia Neuman, *What to Know About Medicare Spending and Financing*, Kaiser Family Found. ("KFF") (Jan. 19, 2023), https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing [https://perma.cc/B5BF-MFGG].

Part II delves into the historical and current participation of Medicare in the prescription drug marketplace, as well as prior efforts to impose price controls.

Next, Part III discusses the impact of Medicare's reimbursement methodology on broader market prescription drug prices. This section argues that, without meaningful negotiating authority, Medicare must rely on average market prices when administering its reimbursement scheme. Industry participants can take advantage of Medicare's formulaic purchasing paradigm to charge exorbitant costs for prescription drugs, knowing that this behemoth buyer is generally obliged to accept such prices. Price inflation in the Medicare market, moreover, bleeds into private markets. Here, Medicare's reliance on market averages for its pricing determinations encourages drug manufacturers to raise drug costs for all purchasers in the market to maximize Medicare reimbursement rates. These financial incentives have contributed to the rising costs of obtaining prescription drugs as well as health insurance coverage.

Notwithstanding the recently-enacted IRA, which provides Medicare with some additional negotiating authority, Medicare remains largely constricted by mandated pricing formulas that are based on market averages. As a result, in many cases drug manufacturers will still be incentivized to inflate the prices paid for drugs by non-Medicare consumers as a necessary prerequisite for raising the prices charged to Medicare beneficiaries.

Part III also discusses the secondary consequences of Medicare policy beyond its contribution to the rising costs of many prescription drugs. In particular, the statutory preclusion under Part D, which prohibits Medicare from making direct purchases of prescription drugs from manufacturers, forces CMS (the agency charged with Medicare's administration) to contract out purchases of prescription drugs to private insurance providers. These providers, in turn, operate within a highly complex network of intermediaries and with often-opaque negotiation processes. Given the amount of capital at stake for Medicare-sponsored drug purchases, the agents who are both directly and indirectly responsible for the flow of Medicare spending have amassed significant sway over the prescription drug market. The ability to direct Medicare spending towards different prescription drugs or treatments has enabled these actors to yield growing influence—and reap greater profits—from Medicare drug sales.

Discussed in Part IV is the effect of Medicare spending on pharmaceutical research and development decisions. Here, Medicare's relative price insensitivity has made its beneficiaries a more attractive market for pharmaceutical research and development spending, leading to voids in innovative treatments for diseases primarily afflicting lower-spend populations, such as individuals enrolled in Medicaid.

Lastly, Part V of this Article advocates for the formation of an independent body charged with coordinated oversight over the pharmaceutical industry. Responsibility for drug pricing should be shouldered by a single agency—one that can take a holistic approach to U.S. healthcare policy, balance the myriad competing interests at stake, and devise solutions that both reduce costs and improve health outcomes. Among its functions, this entity would develop broadly-applicable, value-based prescription drug pricing methodologies that relate drug prices to factors such as clinical benefit and cost of development. Setting value-based drug prices that apply across populations will serve to properly realign drug development incentives and reign in escalating prescription drug costs.

Part I: An Overview of the Prescription Drug Market

A. The Current Landscape of the Prescription Drug Market

In the United States, both new and existing pharmaceutical treatments have experienced sharp price increases over the past twenty years.[15] Indeed, the cost of some common medicines, such as insulin, have increased by over 500%.[16] Importantly, however, while pharmaceuticals' profitability in the U.S. market remains high, our high healthcare spending is not directly correlated with better health outcomes.[17] On the contrary, research shows that while the United States

15. S. REP. NO. 116–120, at 3–4 (2019).

16. *Id.*; Mary Johnson, *Why are Insulin Prices Going Up?*, PHARMAREVIEWER (Feb. 28, 2022), https://pharmareviewer.com/why-are-insulin-prices-going-up/ [https://perma.cc/LT26-KWJ3]. Notably, the IRA contains a provision which limits copays for insulin under Medicare Part D to $35 per month; *See* Juliette Cubanski, Tricia Neuman & Meredith Freed, *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/ [https://perma.cc/B5BF-MFGG].

17. *See* Irene Papanicolas, Liana R. Woskie & Ashish K. Jha, *Health Care Spending in the United States and Other High-Income Countries*, 319 JAMA 1024, 1028 (Mar. 13, 2018).

spends nearly twice as much as ten other high-income countries on medical care, we "performed less well on many population health outcomes."[18] For example, while the U.S. spent 17.8% of GDP on healthcare in the period between 1980 and 2021, such spending was only 11.9% of GDP in the U.K, 12.8% of GDP in Germany, and 12.4% of GDP in France.[19] Yet, the disparities in health outcomes are striking.[20] America, compared to its peers,[21] has the lowest life expectancy at birth and the highest rate of death for treatable and avoidable conditions.[22] Addressing this country's dual difficulties of exorbitant drug costs and relatively poor healthcare outcomes will require surmounting a number of both practical and political obstacles.

First, developing solutions to excessive drug costs requires resolving a number of competing policy considerations. Importantly, prescription drug pricing reform must determine: *what is the fair price of a drug or treatment?* Answering this question will require balancing the complex—and often competing—interests of the many players involved in the pharmaceutical development, delivery, and reimbursement system. Second, given the frequently disparate approaches to determining a reasonable price as it relates to consumers, insurers, and producers of prescription drugs, policy makers must also determine: *for whom is this drug price fair?* Third, efforts for reform will also have to consider the existing piecemeal system of regulation already governing many aspects of the pharmaceutical industry. Additional government intervention will either need to complement existing systems of pharmaceutical governance or supplant these structures with a more comprehensive regime.

18. *See id.* at 1025; *see also How Does the U.S. Healthcare System Compare*, *supra* note 6 (noting that the United States had the highest healthcare spending per capita of any wealthy country in 2021).

19. Munira Z. Gunja, Evan D. Gumas & Reginald D. Williams II, *U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes*, COMMONWEALTH FUND (Jan. 31, 2023), https://doi.org/10.26099/8ejy-yc74 [https://perma.cc/SBR8-S6R2].

20. *Id.*

21. Data was obtained from a 2022 Commonwealth Fund study, where peer countries included Australia, Canada, France, Germany, Japan, the Netherlands, New Zealand, Norway, South Korea, Switzerland, Sweden, and the United Kingdom. *Id.*

22. *Id.*; *see also* Elliot Davis Jr., *Study: U.S. Lags Behind Other Wealthy Countries in Health Outcomes*, U.S. NEWS & WORLD REP. (Feb. 1, 2023, 11:25 AM), https://www.usnews.com/news/best-countries/articles/2023-02-01/u-s-lags-behind-other-wealthy-countries-in-health-outcomes-study-finds [https://perma.cc/GS32-6B9P].

B. What is the "fair price" of a prescription drug?

Reform of the prescription drug industry has proved challenging for a number of reasons. In particular, policymakers have grappled with how to impose price controls without the availability of an "efficient" market to indicate fair value. Unlike perfectly competitive, or "efficient," markets, where prices reflect the optimal value of goods and services, the prescription drug market often operates under "inefficient" conditions, making its prices an unreliable indicator of fair value.[23]

Specifically, the unique characteristics of buyers and sellers in the prescription drug market make it fundamentally different than traditional "efficient" markets for goods and services. On the supply side, sellers (drug manufacturers) will, for a limited-period, operate in monopolistic conditions if their drug products are granted patent protection.[24] On the buyers' side, demand is frequently inelastic, especially in the case of life-saving therapies that lack comparable alternative treatments.[25] Additionally, unlike traditional "cost efficient" markets, different buyers in the prescription drug market are commonly offered wildly different prices, oftentimes awarding those with the largest negotiating power, such as goliath insurance companies, the greatest pricing concessions.[26] Price variation is further exacerbated by the myriad negotiations that take place among a host of pharmaceutical intermediaries, such as wholesalers, pharmacy benefit managers ("PBMs"), and healthcare providers.[27]

To complicate matters further, the answer to "*What is a fair price*?" will vary considerably depending on the market actor being

23. *See* Irena Asmundson, *Back to Basics: Supply and Demand*, 47(2) FIN. & DEV. 47, 49 (June 2010) (explaining that in perfectly efficient markets "there are large numbers of identical suppliers and demanders of the same product, buyers and sellers can find one another at no cost, and no barriers prevent new suppliers from entering the market").

24. *See* Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 859 (2016) (stating that "[t]he primary reason for increasing drug spending is the high price of branded products protected by market exclusivity provisions granted by the US Patent and Trademark Office and the Food and Drug Administration").

25. *Id*. at 861 (discussing reasons why competition often fails to drive prices down or only does so slowly).

26. *See, e.g.*, Jessica Wapner, *How Prescription Drugs Get Their Prices, Explained*, NEWSWEEK (Mar. 17, 2017, 8:00 AM), https://www.newsweek.com/2017/04/14/prescription-drug-pricing-569444.html [https://perma.cc/2NRF-CMWX].

27. *See* Kesselheim et al., *supra* note 24, at 861.

considered. To sellers of prescription drugs, fair prices are likely viewed as more than mere compensation for a drug's cost of production. To drug manufacturers, a "fair price" must account for the variable success rates in drug development and high capital investment costs.[28] Exactly how much more, however, is unclear. Asking buyers about the fair price of a drug is even more nuanced. Should a drug's cost be reflective of factors such as additional years of life provided? Is it morally permissible to assign a dollar value to a year of human life? Additionally, should the price of a drug depend on the status of the buyer as insured or uninsured, or alternatively, on their relative ability to pay out-of-pocket? Accordingly, determining a singular "fair price" of a prescription drug must delicately balance convoluted and often competing interests.

1. METHODS USED IN FAIR PRICE DETERMINATIONS

Countries with "single-payer" healthcare systems, where the government is the exclusive financier of healthcare, often deploy value-based metrics in their fair-pricing determinations.[29] In single-payer countries with universal public insurance programs, government entities will often directly negotiate with drug manufacturers to determine fair pricing models and rates of reimbursement.[30] Frequently, these public insurance systems will establish independent bodies to assess whether a drug's price is reflective of its fair value.[31]

a. Value-Based Metrics

Increasingly, a number of metrics centered around a drug's efficacy and added value have been adopted as standards used in drug price negotiations. Value-based metrics have become critical for payors who are tasked with making coverage determinations that best reflect societal preferences while managing budgets.[32] While the criteria used for value-based pricing models varies, commonly considered metrics include:

28. *Id.* at 863.
29. *Id.* at 864.
30. *Id.* at 860.
31. Examples of these entities include Australia's Pharmaceutical Benefits Advisory Committee, the Canadian Agency for Drugs and Technology in Healthcare, and Germany's Institute for Quality and Efficiency in Healthcare. *See id.*
32. *See* Hemel & Ouellette, Valuing Medical Innovation, *supra* note 12, at 545–54.

- the use of a cost-utility threshold or a monetary value per quality adjusted life year ("QALY") that a drug must exceed in order to be recommended for coverage;
- the comparative effectiveness of a drug relative to existing therapies;
- price comparison to prices charged in other countries; and
- the presence of therapeutic innovation.[33]

Germany, which, like the United States, has elements of both single and multi-payer healthcare systems, utilizes independent bodies to not only assess the value of newly released drugs but also to engage in price negotiations with the drugs' manufacturers.[34] There, drugs that are authorized for market launch by the European Medicines Agency are subsequently subject to clinical evaluation by two different German agencies.[35] While drug manufactures are able to set drug prices at launch, over the next twelve months the Institute for Quality and Efficiency in Health Care ("IQWiG") evaluates the fairness of these initial price determinations based on an assessment of additional clinical benefit offered, looking to factors such as reduced disease duration, survival rates, and reduction in side-effects.[36]

Next, Germany's Joint Federal Committee ("GBA") combines the IQWiG reports with testimony, which is gathered at public hearings, from the manufacturer as well as from patient advocacy groups and associations representing physicians.[37] If the drug's "added therapeutic benefit" exceeds existing standards of care, then the national health insurer will engage in price negotiations with the drug's manufacturer.[38]

33. *See generally id.*

34. *See Drug Assessment and Pricing in Germany*, BERKELEY CTR. FOR HEALTH TECH., https://bcht.berkeley.edu/drug-assessment-and-pricing-germany (last visited Mar. 19, 2024) [hereinafter *Drug Pricing in Germany*] [https://perma.cc/D86X-3KY5].

35. *See id.*

36. *Id.*; *see* Danielle Kost, *Germany May Have the Answer for Reducing Drug Prices*, HARV. BUS. SCH.: WORKING KNOWLEDGE (Sept. 11, 2019), https://hbswk.hbs.edu/item/germany-may-have-the-answer-for-reducing-drug-prices [https://perma.cc/5Y62-H6BX].

37. *See Drug Pricing in Germany*, *supra* note 34.

38. Negotiations are conducted by Germany's National Association of Statutory Health Insurance Funds (Spitzenverband Bund der Krankenkassen – GKV-SV). *See* MARTIN WENZL & VALÉRIE PARIS, OECD, PHARMACEUTICAL REIMBURSEMENT AND PRICING IN GERMANY 6 (2018), https://www.oecd.org/els/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf [https://perma.cc/Z8DW-2U35].

If no agreement on pricing can be reached through negotiation, the drug's price is established through arbitration.[39]

b. Comparative Effectiveness Research

Efforts to shift to value-based metrics in this country have propelled the development of a growing body of comparative effectiveness research ("CER") to "provide data on the relative merits of different strategies to prevent, diagnose or treat illness."[40] Already, the U.S. has devoted over $1 billion in funding to bodies such as the Institute of Medicine to amass data which can be used to identify the highest-value care and the most pressing medical needs.[41]

CER differs from the existing body of data collected by the Food and Drug Administration ("FDA"). Existing data collected by the FDA typically compares a new drug to a placebo or to no treatment at all, which offers insight into safety and effectiveness, yet lacks information about the drug's merits relative to other treatment options.[42] Accordingly, a more robust data set is needed to "develop a healthcare delivery system that provides better outcomes for each kind of patient at much lower cost."[43]

CER seeks to fill this information void by directly comparing different treatments available and their performance across population demographic characteristics, such as sex, ethnicity, and age.[44] As stated in the Institute of Medicine's report, *Initial National Priorities for Comparative Effectiveness Research*, CER seeks to engage in a relative evaluation of treatment options "to discern what works best for which

39. *See id.* at 7.

40. David Meltzer, Anirban Basu & Rena Conti, *The Economics of Comparative Effectiveness Studies: Societal and Private Perspectives and their Implications for Prioritizing Public Investments in Comparative Effectiveness Research*, 28 PHARMACOECONS. 843, 843 (2010).

41. Four areas of research are needed to inform healthcare policy; "(1) baselines for evaluations, such as disease models and natural histories; (2) safety; (3) comparative effectiveness of interventions; and (4) comparative effectiveness of treatment strategies and practice patterns." LEIGHANNE OLSEN, CLAUDIA GROSSMANN & J. MICHAEL MCGINNIS, INST. MED. NAT'L ACADS., LEARNING WHAT WORKS: INFRASTRUCTURE REQUIRED FOR COMPARATIVE EFFECTIVENESS RESEARCH 59 (2011), https://www.ncbi.nlm.nih.gov/books/NBK64791/ [https://perma.cc/8PBV-7QJG].

42. *See id.* at 97.

43. *Id.* at 59.

44. INST. MED. NAT'L ACADS., INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH 102–03 (2009), https://www.multiplechronicconditions.org/wp-content/uploads/2023/01/iom-cer-1.pdf [https://perma.cc/35YW-KYCK].

patients and populations" and to use these insights to inform a healthcare system's long-term strategy.[45]

c. Reliance on Free Market Principles

In the United States, the prescription drug market is composed of both public and private purchasers. Individuals typically do not engage in direct participation of the prescription drug market and, instead, rely on insurance providers to negotiate the cost of their prescriptions. These larger purchasers, such as public and private insurance providers, then contract with additional intermediaries, such as pharmacy benefit managers ("PBMs"), who negotiate on their behalf for rebates and other pricing concessions from the manufacturers.[46] The methodologies used by these large drug purchasers in price negotiations vary considerably, but generally seek to balance cost considerations with healthcare needs.[47]

In the U.S. market, regulation of prescription drug pricing relies heavily on "free market" forces, i.e., the purchasing and selling decisions made by private market purchasers, to ensure fair pricing for consumers.[48] Unlike other countries that directly negotiate drug prices with manufacturers, the U.S. government generally abstains from such active participation and regulation of the prescription drug market. Here, regulators have largely foregone the adoption of value-based metrics or CER to establish "fair" drug prices. In addition to avoiding greater regulatory oversight of private markets, the U.S. government has also sought to avoid making its own assessment of a drug's fair value in its own drug purchases under public insurance programs. In fact, the 2010

45. *Id.* at xiii.

46. *See* Kesselheim et al., *supra* note 24, at 862.

47. *See, e.g.*, Sarah Kliff & Josh Katz, *Hospitals and Insurers Didn't Want You to See These Prices. Here's Why*, N.Y. TIMES (Aug. 22, 2021), https://www.nytimes.com/interactive/2021/08/22/upshot/hospital-prices.html [https://perma.cc/S6SC-XJFV].

48. Basic principles of market efficiency dictate that competition is good for the consumer. With multiple sellers in a marketplace, consumers are afforded the discretion to purchase comparable goods based on the lowest price offered, driving markets to reach "efficiency" or prices that reflect the value of goods sold. *See, e.g.*, Heather Boushey & Helen Knudsen, *The Importance of Competition for the American Economy*, WHITE HOUSE (July 9, 2021), https://www.whitehouse.gov/cea/written-materials/2021/07/09/the-importance-of-competition-for-the-american-economy/ [https://perma.cc/348Q-CQJ6].

Patient Protection and Affordable Care Act ("ACA")[49] specifically denied CMS the ability to use CER-based recommendations in CMS decision-making.[50] Instead, the federal government, in the drug purchasing context, has historically attempted to avoid disruption of market forces by relying on the prices paid by other private market purchasers.[51] For example, government-sponsored programs typically make pricing determinations through the use of mandatory formulas based on average market prices.[52]

C. The Pharmaceutical Supply Chain

1. KEY ACTORS IN THE PHARMACEUTICAL SUPPLY CHAIN

The drug prices paid by individuals at the pharmacy counter are determined by an intricate series of negotiations made between intermediaries along the pharmaceutical supply chain. While most consumers are familiar with the intermediaries responsible for the final stages of drug delivery, such as the dispensing pharmacy or medical professional administering treatment, the preceding network of buyers and sellers of prescription drugs operates largely in the shadows of public awareness. Notwithstanding their lack of notoriety, these pharmaceutical intermediaries are pivotal in determining consumers' ultimate prescription drug costs. Below is an outline of the players involved.

a. Supply Chain from Manufacturer to Consumer

First, the **drug's manufacturer** will typically set drug prices and sell its products, in bulk, to **wholesale distributors**.[53] Wholesale

49. Patient Protection and Affordable Care Act, Pub. Law No. 111-148, 124 Stat. 119 (2010).

50. *See* 42 U.S.C. §§ 1320e(8)(A)(iv), -1(e) (prohibiting the use of CER-based recommendations as "practice guidelines, coverage recommendations, payment, or policy recommendations").

51. *See* Susan Weidner, Michael Diaz, Cass Schaedig & Lucio Gordan, *Observations Regarding the Average Sales Price Reimbursement Methodology*, 27 AMJC 156, 156 (2021), https://www.ajmc.com/view/observations-regarding-the-average-sales-price-reimbursement-methodology [https://perma.cc/EAQ4-YC2W].

52. *See id.* at 157.

53. Today, most drug manufacturing is done by large multinational firms, such as Pfizer, Merck, and Novartis. Wholesale distributors have experienced similar consolidation, with the top three wholesalers accounting for most of the market share. *See, e.g.*, HEALTH STRATEGIES CONSULTANCY LLC, KKF, FOLLOW THE PILL:

distributors then sell the prescription drugs to **pharmacies**, who generally buy an inventory of drugs to have available for prescription orders. Once an **individual** picks up their prescription, the pharmacy will either charge the individual fully out-of-pocket (potentially with a discount offered) for the cost of the drug, or, if they are insured, the pharmacy will charge a share of the drug's cost to an insurance provider.

b. Intermediary Negotiations

Concurrently, however, an additional series of negotiations takes place between the **insurance provider** and the **pharmacy** that is facilitated by **PBMs**, who are a less-known, but often pivotal, determinant of drug prices.[54] Both private and Medicare-sponsored insurance plans[55] contract with PBMs to, among other functions, negotiate drug prices and rebates[56] from other intermediaries in the pharmaceutical supply chain. As a result, PBMs are highly connected middlemen in the convoluted drug market and can exert significant influence on the prices of prescription drugs.[57]

2. PRICING METRICS USED IN PRESCRIPTION DRUG MARKET

The initial prices set by drug manufacturers at the start of this supply chain are frequently unreflective of the actual cost of drugs to purchasers.[58] Along this complex supply chain, drug intermediaries exchange a variety of different pricing concessions, discounts, and rebates

UNDERSTANDING THE U.S. Commercial PHARMACEUTICAL SUPPLY CHAIN 1 (2005), https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf [https://perma.cc/XNU2-C8XC].

54. *Pharmacy Benefit Manager*s, NAIC (June 1, 2023), https://content.naic.org/cipr-topics/pharmacy-benefit-managers [https://perma.cc/7WLH-BRYM].

55. Plans sponsors under Medicare Part D contract with PBMs to provide nearly 75% of drug benefit management services for Medicare. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-19-498, MEDICARE PART D: USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION 14 (2019).

56. PBMs earn income from the administrative fees charged for their services, as well as by keeping portions on the rebates and discounts that are negotiated with drug manufacturers. *See* NAIC, *supra* note 54.

57. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-19-498, MEDICARE PART D: USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION 14 (2019).

58. *See id*. at 58.

that generally reduce net prices.[59] Due to the opacity of these negotiations, however, the magnitude of pricing discounts afforded to different purchasers is typically unknown. As stated by Lisa Ellis in her article, *Snapshot of the American Pharmaceutical Industry*, "[w]hat this means in layman's terms is that there are different prices for the same drug, depending on who is paying the bill."[60] Pricing variability extends to individual consumers, who are often subject to highly disparate prescription costs. This price variation is apparent in the myriad terms available to describe the many "prices" attached to a single drug.

For example, a drug's **Wholesale Acquisition Cost ("WAC")** is the "list" price set by drug manufacturers for wholesalers or other direct purchasers.[61] Importantly, however, a drug's WAC does not include rebates, discounts, and pricing concessions, and thus does not accurately capture the revenue ultimately received by the manufacturer.[62] Instead, a drug's **net price** represents actual revenue earned by a drug manufacturer from the sale of a drug.[63] This figure accounts for drug rebates, distribution fees, product returns, and other discounts.[64]

The difference between the WAC and the net price of a drug reveals the size of pricing concessions afforded to intermediaries along the pharmaceutical supply chain. As stated by Adam J. Fein in his article, *Gross-to-Net Bubble Update: Net Prices Drop (Again) at Six Top Drugmakers*, recent trends show that the difference between list and net prices is growing, indicating that "brand-name manufacturers earn far less revenue than list prices suggest."[65] Fein's research suggests that, in 2020, drug manufacturers sold their products "for less than half of the list price."[66] Pharmaceutical giant Janssen, for example, paid over $29 billion in fees, rebates, and discounts.[67] Another report shows that

59. Lisa Ellis, *Snapshot of the American Pharmaceutical Industry*, HARV. T.H. CHAN SCH. PUB. HEALTH (July 14, 2016), https://www.hsph.harvard.edu/ecpe/snapshot-of-the-american-pharmaceutical-industry/ [https://perma.cc/7JFP-QPGR].

60. *Id.*

61. Adam J. Fein, *Gross-to-Net Bubble Update: Net Prices Drop (Again) at Six Top Drugmakers*, DRUG CHANNELS (Apr. 14, 2021), https://www.drugchannels.net/2021/04/gross-to-net-bubble-update-net-prices.html [https://perma.cc/B79W-5QFT].

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

pricing discounts increased from 23% in 2007 to 51% in 2018.[68] As these disparities indicate, merely identifying the actual price of a prescription drug is exceedingly difficult, adding yet another wrinkle to assessing whether that drug price is fair.

3. GOVERNMENT PARTICIPATION IN THE PRESCRIPTION DRUG MARKET

Growing public dissatisfaction with the rising costs of pharmaceutical treatments has invigorated demand for greater government involvement in establishing "fair" prescription drug prices.[69] These efforts have been met with fierce opposition from industry participants, who argue that government intervention in the prescription drug market will threaten pharmaceutical innovation.[70] Often absent from these debates, however, is an acknowledgement that the government *has already intervened* in this market. In fact, it is one of its largest participants.[71]

The U.S. prescription drug market is mainly supported by four sources of funding: private health insurance (29% share); Medicare (21% share); Medicaid (18% share); and out-of-pocket spending (11% share),[72] making the U.S. government the largest purchaser of prescription drugs in the aggregate. Indeed, in 2022 Medicare and Medicaid spending alone accounted for roughly 40% of total healthcare spending in the United States.[73] The U.S. government purchases prescription drugs both as part of federal agency employee health plans, including the plans of the Department of Veterans Affairs and the Department of Defense, as well as through public insurance options, like Medicare and Medicaid.[74]

68. *See* Inmaculada Hernandez, Alvaro San-Juan-Rodriguez, Chester B. Good & Walid F. Gellad, *Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007–2018*, 323 JAMA 854, 855 (2020) (noting that although pricing discounts offset a portion of recent drug price increases, "there was still a substantial increase in net prices over this period").

69. Thomas R. Oliver, Phillip R. Lee, & Helene L. Lipton, *A Political History of Medicare and Prescription Drug Coverage*, 82 MILBANK QUARTERLY 283, 327–29 (2004).

70. *See id*.

71. *See National Health Expenditures 2022 Highlights*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 13, 2023), https://www.cms.gov/newsroom/fact-sheets/national-health-expenditures-2022-highlights [https://perma.cc/F4KV-YAN9].

72. *Id*.

73. *Id.*

74. CONG. BUDGET OFF., A COMPARISON OF BRAND-NAME DRUG PRICES AMONG SELECTED FEDERAL PROGRAMS 1 (2021), https://www.cbo.gov/system/files/

Given the magnitude of federal spending on prescription drugs and its undoubtedly significant effect on the behavior of the pharmaceutical industry, calls to "keep the government out" of the prescription drug market necessarily falter, as the government is already a major player in the arena. Thus, notwithstanding attempts to minimize government involvement in the prescription drug market by precluding the government from playing a direct role in setting drug prices, public insurance programs clearly exert substantial influence on both pharmaceutical innovation and pricing strategies. Accordingly, effective drug pricing reform requires addressing the consequences of the government's pricing approach and whether its historical passivity is warranted.

PART II: AN OVERVIEW OF THE MEDICARE SYSTEM

A. Medicare Program Overview

Medicare provides public health insurance to almost 64 million individuals, including the elderly and those with certain long-term disabilities.[75] Recent reports show that roughly 55.5 million individuals were eligible for Medicare due to being over 65 years old and 8.3 million individuals were eligible due to a qualifying disability.[76]

Medicare's spending has markedly increased since its inception, totaling $829 billion in 2021, or roughly 10% of the federal budget.[77] Spending is also expected to grow significantly in future years, reaching an estimated $1.02 trillion in 2024.[78] A number of factors are expected to exacerbate Medicare's growing financial strain. First, the

2021-02/56978-Drug-Prices.pdf [hereinafter CBO, COMPARISON OF BRAND-NAME DRUG PRICES] [https://perma.cc/E3AJ-TN65].

75. *See* BDS. TRS. FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS, 2022 ANNUAL REPORT 8 (2022), https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf [https://perma.cc/8VWM-MDFJ].

76. Medicare is available to those in the U.S. who are age 65 or older and who have paid Medicare payroll taxes for at least 10 years, as well as certain younger people who have received Social Security disability benefits for at least two years or who have end-stage renal disease or amyotrophic lateral sclerosis. *See id.*

77. *See* Cubanski & Neuman, *supra* note 14 (stating that "[f]unding for Medicare, which totaled $888 billion in 2021, comes primarily from general revenues (46%), payroll tax revenues (34%), and premiums paid by beneficiaries (15%).").

78. *Id.*; *see Government's Mandatory Health Care Spending Now Exceeds Entire Discretionary Budget,* Congressional Budget Off. (Jan. 26, 2024).

elderly demographic in the United States is expected to grow substantially, as the baby boomer generation will collectively age beyond 65 years by 2030.[79] Second, in addition to a growing number of Medicare beneficiaries, the cost of coverage for each of these beneficiaries has risen significantly.[80] Third, birth rates have declined, leading to a smaller base of working individuals contributing to Medicare's funding.[81]

Medicare consists of four main insurance programs: Part A, Part B, Part C and Part D.[82] While Medicare's prescription drug coverage falls predominately under Part B and Part D, details of all four programs are outlined below:

- **Medicare Part A:** (hospital insurance) provides beneficiaries inpatient services at hospitals, nursing homes, and hospice care facilities.[83]
- **Medicare Part B:** (medical insurance) offers coverage of outpatient and ancillary medical services, such as ambulance transportation, in addition to covering certain prescription drugs and treatments that are administered in physician offices and hospital outpatient departments.[84] Roughly half of the $829 billion Medicare spent in 2021[85] was used to finance Medicare Part B.[86] Part B covers

79. *Older People Projected to Outnumber Children for First Time in U.S. History*, U.S. CENSUS BUREAU (Oct. 8, 2021), https://www.census.gov/newsroom/press-releases/2018/cb18-41-population-projections.html [https://perma.cc/D8KF-BLZC].

80. *See* Cubanski & Neuman, *supra* note 14.

81. *Why is the U.S. Birth Rate Declining?*, POPULATION REF. BUREAU (May 6, 2021), http://www.prb.org/resources/why-is-the-u-s-birth-rate-declining [https://perma.cc/MFS5-MN59].

82. Under Part C, beneficiaries may choose to receive benefits from either Medicare's fee-for-service ("FFS") program or through a subsidized private insurance program, Medicare Advantage, *see* CONG. BUDGET OFF., BASELINE PROJECTIONS: MEDICARE, 1–4 (2022), https://www.cbo.gov/system/files/2022-05/51302-2022-05-medicare.pdf [hereinafter CONG. BUDGET OFF. BASELINE PROJECTIONS] [https://perma.cc/D67V-6HS8]; *see also* MEDPAC, THE MEDICARE ADVANTAGE PROGRAM: STATUS REPORT AND MANDATED REPORT ON DUAL ELIGIBLE SPECIAL NEEDS PLANS, 409–11 (2022), https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch12_SEC.pdf [https://perma.cc/R6FK-BXHP].

83. CONG. BUDGET OFF., BASELINE PROJECTIONS, *supra* note 82, at 1.

84. *Id.*

85. *See* Cubanski & Neuman, *supra* note 14.

86. Medicare Part B also covers a number of mandated therapies and certain drugs provided by pharmacies, like inhalers and certain oral anticancer, oral antiemetic, and immunosuppressive drugs. STEVEN SHEINGOLD, ELENA MARCHETTI-BOWICK, NGUYEN NGUYEN, & K. ROBIN YABROFF, ASPE, MEDICARE PART B DRUGS: PRICING AND INCENTIVES 1 (2016), https://aspe.hhs.gov/sites/default/files/private/pdf/187581/PartBDrug.pdf [https://perma.cc/K2A6-2W7A].

certain critical treatments for diseases such as cancer and rheumatoid arthritis.[87] Notably, substantial drug price increases are often associated with Part B drugs.[88] "In 2020, government reports found that Medicare fee-for-service Part B drug spending increased 8.1% annually in the decade from 2006 to 2017, twice as fast as Part D drug spending."[89]

- **Medicare Part C:** (Medicare Advantage private insurance program) offers private insurance options for beneficiaries enrolled in both Part A and Part B.[90]
- **Medicare Part D**: (prescription drugs) offers subsidized access to private insurers for prescription drug coverage; enrollment is contingent upon beneficiaries' payment of monthly premiums.[91] Part D was added in 2003 under the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA").[92] As of 2022, 49 million of Medicare's 65 million beneficiaries are enrolled in Part D.[93]

87. These include services such as ambulance services, mental health treatments, certain inpatient healthcare, partial hospitalization; and limited outpatient prescription drugs (such as oral cancer drugs, immunosuppressive drugs, injectable and infused drugs). *See* HEALTH AFFAIRS, PRESCRIPTION DRUG PRICING 1 (2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000171/listitem/healthpolicybrief_171.pdf [https://perma.cc/UZJ8-PK2Z].

88. *Id.*

89. Walid F. Gellad & Inmaculada Hernandez, *Pharmaceutical Spending in Fee-for-Service Medicare: Looking Ahead to the Inflation Reduction Act*, 328 JAMA 1502, 1502 (2022).

90. *See* WAFA TARAZI, PETE WELCH, NGUYEN NGUYEN, ARIELLE BOSWORTH, STEVEN SHEINGOLD, NANCY DE LEWE & BENJAMIN D. SOMMERS, ASPE, MEDICARE BENEFICIARY ENROLLMENT TRENDS AND DEMOGRAPHIC CHARACTERISTICS 2 (2022), https://aspe.hhs.gov/sites/default/files/documents/f81aafbba0b331c71c6e8bc66512e25d/medicare-beneficiary-enrollment-ib.pdf [https://perma.cc/9QRD-CRHL].

91. The primary source of Part D funding is general federal revenues. Since 2011, high-earning Part D Medicare beneficiaries have been required to pay higher premiums. *See, e.g.*, Bryan Willard, *An Easier Pill to Swallow: Subscription Model Agreements* as a *Solution to the Government's Prescription Drug Pricing Crisis*, 30 S. CAL. INTERDISC. L. J. 587, 590–92 (2021).

92. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

93. *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/ [hereinafter KKF, *Medicare Part D*] [https://perma.cc/L2FZ-DHGR].

B. Medicare's Prescription Drug Program

Given the magnitude of its purchases, Medicare's prescription drug program has become a major driver of revenue for the pharmaceutical industry.[94] Accordingly, drug purchases subsidized by the program heavily influence both the types of drugs that are brought to market and their costs to different purchasers.[95] Importantly, however, while payments provided by Medicare exert significant influence over the prescription drug market, this government buyer often has little control over how this influence is used. As discussed below, restrictions that limit Medicare's direct participation in the prescription drug market[96] have inadvertently contributed to the myriad problems currently plaguing the U.S. pharmaceutical sector, such as rising drug prices and, as will be discussed more fully in Part III, an increasingly complex pricing system that often involves opaque payment schemes and powerful intermediaries.

Without adequate safeguards in place, Medicare's passive participation in the prescription drug market has made it susceptible to manipulation by industry participants, who can often maximize profits when Medicare prices are highest. Here, poorly-considered program design has "incentivize[d] firms to locate regulatory niches where they feel safe from competition on the merits with rivals."[97] Discussed below are the statutory limitations set forth in the 21st century's three major Medicare reforms:

- The 2003 Medicare Modernization and Improvement Act ("MMA")
- The 2010 Affordable Care Act ("ACA")
- The 2022 Inflation Reduction Act ("IRA")

1. THE NON-INTERFERENCE CLAUSE UNDER THE MMA

The past twenty years of Medicare reform is best understood with insight into the contentious political climate that transformed Medicare policy from what was once an area with bipartisan support into a tool of political weaponry. Starting in 1995, Republicans and Democrats

94. Willard, *supra* note 91, at 592.
95. *See id*.
96. *See id.* at 594.
97. Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* 1 (Hutchins Ctr. on Fiscal & Monetary Pol'y Brookings, Working Paper #30, 2017), https://www.brookings.edu/wp-content/uploads/2017/05/wp30_scottmorton_competitioninpharma1.pdf [https://perma.cc/GG2D-32AD].

began to villainize certain Medicare policies across party lines in order to achieve success in a hotly-divided political environment.[98] Thomas Oliver, in *A Political History of Medicare and Prescription Drug Coverage*, describes the shift in Medicare policy in the mid-nineties as "transform[ing] much of Medicare policymaking from a deliberative, bipartisan process into a highly polarized, deadlock debate."[99] As a result, the enactment of the MMA in 2003 reflects an attempt by policymakers to contain Medicare costs while still appeasing the interests of both the pharmaceutical industry and program beneficiaries.[100] As described by Michael T. Heaney in *Brokering Health Policy: Coalitions, Parties, and Interest Group Influence*, certain interest groups, such as Pharmaceutical Research and Manufactures of America (PhRMA), representing much of the pharmaceutical industry, and AARP, primarily representing the elderly population, became "positioned to extract their pound of flesh" from Medicare policy.[101]

The expansion of Medicare Part D in 2003 reveals Republican efforts to resolve the dissonance caused by expanding "big government" and public social programs by adorning Part D with "free market" policies.[102] Specifically, Part D was designed to avoid Medicare's direct participation in the prescription drug market.[103] As an important result, the expansion of Medicare under Part D contains a statutory prohibition, known as the non-interference clause, barring CMS from directly negotiating prices and coverage with drug manufacturers, pharmacies, and prescription drug plan ("PDP") sponsors.[104]

This non-interference clause reads:

> In order to promote competition under this part and in carrying out this part, the Secretary–
>
> > (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors;
> >
> > (2) may not require a particular formulary, except as provided under section 1395w-104(b)(3)(I) of this title; and

98. Oliver et al., *supra* note 69, at 302.
99. *Id.* at 289.
100. *Id.* at 296.
101. Michael T. Heaney, *Brokering Health Policy: Coalitions, Parties, and Interest Group Influence*, 31 J. HEALTH POL., POL'Y & L. 887, 929 (2006).
102. Oliver et al., *supra* note 69, at 332.
103. *See* Willard, *supra* note 91, at 592–93.
104. *See* 42 U.S.C. § 1395w-111(i).

> (3) may not institute a price structure for the reimbursement of covered part D drugs, except as provided under part E of subchapter XI.[105]

Additionally, by statute, Medicare Part D insurers must cover all drugs that have only one or two available treatments, as well as drugs available for six "protected classes" of treatments, including: antiretrovirals, antidepressants, antipsychotics, antineoplastics, immunosuppressants, and anticonvulsants.[106] Without the authority to refuse to cover drugs in these therapeutic categories, Medicare cannot credibly threaten to forgo the purchase of such drugs because their prices are excessive. Without this negotiating leverage, Medicare fundamentally lacks the ability to walk away from a bad deal, making it highly susceptible to price inflation by industry participants.[107]

Precluded from directly engaging in price negotiations, Medicare under Part D provides prescription drug coverage by subsidizing access[108] to certain private insurance plans ("plan sponsors").[109] As part of their contracted agreements with Medicare, plan sponsors act on behalf of Medicare to negotiate with various actors in the healthcare industry.[110] By mandated use of plan sponsors, Medicare is forced to assume a passive role in its purchase of prescription drugs, divesting the program of discretionary authority over the billions of dollars that flow

105. *Id.*

106. Familiar examples of these drugs include anti-seizure medication, antidepressants, non-intravenous cancer drugs, HIV/AIDS drugs, immunosuppressants for the treatment of transplant rejection, and HMG-CoA reductase inhibitors and beta blockers. *See* Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 12, at 540.

107. Rachel Sachs, *The Accidental Innovation Policymakers*, 72 DUKE L. J. 1431, 1476–77 (2023) [hereinafter Sachs, *The Accidental Innovation Policymakers*].

108. The Part D program, which is voluntarily available to Medicare beneficiaries, is contingent upon the beneficiary's payment of an additional monthly premium. The average basic monthly premium for Medicare Part D is projected to be approximately $31.50 in 2023, down 58 cents from the average monthly premium in 2022. *See* Dana Shilling, *D is for Decade: Ten Years of Medicare Part D*, 272 ELDER L. ADVISORY 1, 1 (Nov. 2013) (noting that "[p]remium subsidies are available for low-income Medicare enrollees, subject to asset limitations"); *see also* Sarah O'Brien, *Average Premiums for Medicare Prescription Drug Coverage Are Set to Dip to About $31.50 a Month in 2023, Deductibles to Rise*, CNBC (Aug. 2, 2022, 12:59 PM), https://www.cnbc.com/2022/08/02/average-premiums-for-medicare-part-d-are-set-to-dip-next-year.html [https://perma.cc/WK9V-J9AA].

109. Those enrolled in Medicare Part D may either supplement an existing Medicare Advantage Plan, such as those offered by health maintenance organizations ("HMOs") and preferred provider organizations ("PPOs") or elect a stand-alone prescription drug plan. *See* KKF, *Medicare Part D*, *supra* note 93.

110. *See* Willard, *supra* note 91, at 594.

between drug manufacturers, PBMs and pharmacies in the purchase of beneficiaries' prescription drugs and treatments.[111]

2. PROHIBITION ON THE USE OF VALUE-BASED PRICING INITIATIVES (SUCH AS CER AND QALY) UNDER THE ACA

The 2010 enactment of the ACA included a number of significant changes to Medicare's prescription drug policy, in addition to its reform of healthcare coverage for the broader population.[112] In particular, efforts were made under the ACA to incorporate value-based metrics in Medicare's drug purchases, such as comparative effective research ("CER")[113] and Quality Adjusted Life Years ("QALY"), described more fully in Part I. Discussion surrounding the use of value-based metrics, however, provoked significant backlash from the pharmaceutical industry.[114] This opposition ultimately resulted in the ACA's statutory prohibition against the use of this criteria in Medicare's drug purchases.[115]

a. CER

In order to develop comparative effectiveness research in the U.S., the ACA created the Patient Centered Outcomes Research Institute ("PCORI"), an independent, nonprofit research organization[116] devoted to evaluating the relative clinical effectiveness of two or more medical treatments, services, or health practices.[117] The addition of CER topics

111. *Id.* at 592–93.

112. Notably, the ACA restructured Medicare Advantage, freezing the maximum federal reimbursement for Medicare Advantage plans at 2010 levels to bring the program's costs in line with Medicare fee-for-service spending. The ACA also prohibited insurance providers from excluding individuals with pre-existing conditions from coverage. Additionally, the ACA created more affordable insurance options for those without government or employer coverage. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE & MEDICAID MILESTONES 1937-2015, 8 (2015), https://www.cms.gov/About-CMS/Agency-Information/History/Downloads/Medicare-and-Medicaid-Milestones-1937-2015.pdf [https://perma.cc/B5M3-5WYG].

113. For a broader discussion on CER, *see infra* Part I.B.1.b.

114. *See* Steven D. Pearson, *Cost, Coverage, and Comparative Effectiveness Research: The Critical Issues for Oncology*, 30 J. CLINICAL ONCOLOGY 4275, 4275–77 (2012).

115. *See id.*

116. *See About PCORI*, PCORI, https://www.pcori.org/about/about-pcori [https://perma.cc/DX7Z-NGL9] (last visited Mar. 19, 2024).

117. *See* 42 U.S.C. § 1320e(b); *see also* Jason John Luke, *The Role of Comparative Effectiveness Research in Developing Clinical Guidelines and Reimbursement Policies*, 13 AM. MED. ASS'N J. ETHICS 42, 43–44 (2011), https://journalofethics.ama-assn.org/sites/joedb/files/2018-05/pfor1-1101.pdf [https://perma.cc/56VF-EL95].

to the ACA, however, triggered substantial pushback over its use in Medicare's reimbursement policy.[118] Steven D. Pearson, in *Coverage, and Comparative Effectiveness Research: The Critical Issues for Oncology*, explains how the ultimate fate of the application of CER was marred by political divide.[119] According to Pearson, "any chance for a reasonable public discussion of the possible uses and misuses of CER was drowned out by the endemic vitriol of the political environment surrounding the ACA."[120] Ironically, as a consequence of the formation of the PCORI, the ACA ultimately imposed several restrictions on the use of CER and value-based pricing initiatives in Medicare spending.[121] For example, under the ACA, the PCORI is prohibited from using its findings as "practice guidelines, coverage recommendations, payment, or policy recommendations."[122]

b. QALY

Additionally, section 1182(e) of the ACA prohibits the use of the QALY[123] metric as a threshold to determine coverage, reimbursement, or incentive programs under Medicare.[124] As mentioned in Part I, a QALY is the widely accepted standard for measuring how well different medical treatments improve both the quality and length of patients' lives.[125] Outside the Medicare program, QALY is commonly used in fair-pricing determinations to assess a drug's relative value and therapeutic benefit.[126]

Thus, PCORI has been tasked with generating a large body of research surrounding the comparative effectiveness of different

118. *See* Pearson, *supra* note 114, at 4275–77.
119. *See id*.
120. *Id*. at 4276.
121. 42 U.S.C. § 1320e(d)(8)(A)(iv).
122. *Id.*
123. *See Cost-Effectiveness, the QALY, and the evLYG*, INST. FOR CLINICAL & ECON. REV., https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/ (last visited Mar. 19, 2024) [https://perma.cc/Z994-9JFK].
124. *See* Henry A. Glick, Sean McElligott, Mark V. Pauly, Richard J. Willke, Henry Bergquist, Jalpa Doshi, Lee A. Fleisher, Bruce Kinosian, Eleanor Perfetto, Daniel E. Polsky & J. Sanford Schwartz, *Comparative Effectiveness and Cost-Effectiveness Analyses Frequently Agree on Value*, 34 HEALTH AFFS. 805, 805 (2015).
125. *See supra* Part I.B.1.a.
126. *See* Nitzan Arad & Mark B. McClellan, *Drug Pricing Reform in the Inflation Reduction Act*: *What Are the Implications? Part 1*, HEALTH AFFS. FOREFRONT (Dec. 14, 2022), https://www.healthaffairs.org/content/forefront/drug-pricing-reform-inflation-reduction-act-implications-part-1 [https://perma.cc/SDK8-EU4K].

treatment options but cannot actually use these findings to provide guidance or recommendations to Medicare. In sum, ACA negotiations brought CER into focus as a part of Medicare policy, but the statute, as ultimately enacted, significantly curtailed its use.

3. 2022 IRA—LIMITED EXPANSION OF MEDICARE'S NEGOTIATING AUTHORITY

The IRA, which was signed into law on August 16, 2022, has been hailed as the most significant prescription drug legislation enacted since the MMA.[127] Subtitle B of the IRA includes five provisions related to Medicare's existing payment scheme and scope of coverage for prescription drugs, described below:

- **Part 1—Maximum Fair Price Determinations:** Part 1 of the IRA's Medicare reform implements a price negotiation scheme for certain high-cost drugs covered by Medicare.[128] Under Part 1, the Secretary of Health and Human Services ("HHS") is granted the authority to set a maximum fair price ("MFP") for purchases of certain prescription drugs covered under Medicare Part B and Part D.[129]
- **Part 2—Inflation-linked Rebates:** Part 2 requires drug manufacturers to pay inflation-based rebates for certain drugs covered under Medicare Part B and Part D if their prices increase more quickly than the rate of inflation.[130]
- **Part 3—Out-of-Pocket Cost Controls:** Part 3 reduces the amount of out-of-pocket expenses of Medicare beneficiaries.[131]
- **Part 4—Postponement of the "Rebate Rule":** Part 4 postpones the implementation of amendments to the "Rebate Rule," a statutory safe harbor to the Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act), [132] until January 2032.
- **Part 5—Miscellaneous**: Part 5 covers miscellaneous provisions.[133]

127. Inflation Reduction Act of 2022, Pub. L. No. 117–169, 136 Stat. 1818 (2022); *see* Arad & McClellan, *supra* note 126.

128. 42 U.S.C § 1320f; Cubanski et al., *supra* note 16.

129. *Id.*

130. *Id.*

131. *Id.*

132. *See* Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340 (Feb. 6, 2019) (to be codified at 42 C.F.R. pt. 1001).

133. *See* Inflation Reduction Act of 2022, Pub. L. No. 117–169, 136 Stat. 1818, 1896.

While these provisions importantly attempt to arm Medicare with greater discretion over its prescription drug price determinations, their effectiveness is likely to be quite limited. Drug pricing controls in the IRA, such as inflation-linked rebates, can be circumvented through higher launch prices.[134] Similarly, the number of drugs eligible for the IRA's negotiation provisions, at least for the next several years, is severely restricted.[135] In addition to its limited scope, the recent reform is also likely to have a number of unfortunate unintended consequences, such as reducing the number of Part D-participating plans, raising the prices of many drugs (including generics), and reducing spending on pharmaceutical research and development in areas of high public health need. Further evaluation of the IRA is discussed below.

c. Medicare's Fair Price Determinations

Under Section 11001 of the IRA, the Secretary of HHS is tasked with determining the maximum fair price, or MFP, that Medicare should pay for a limited number of its covered prescription drugs and treatments.[136] For a selected drug, CMS will base its MFP determination on a number of factors, including the price of therapeutic alternatives and the manufacturer's cost of development.[137]

While the relative weighting of these factors is not yet certain, the IRA dictates that the MFP will be capped by a "ceiling," or maximum price limit, at the *lower* of either:

> (1) the average non-federal average manufacturer price (non-FAMP) for 2021 or;
>
> (2) for Part D drugs, the average Medicare negotiated price net of rebates and concession received by PBMs; or

134. MEDPAC, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 83–85 (2022), https://www.medpac.gov/document/june-2022-report-to-the-congress-medicare-and-the-health-care-delivery-system/ [hereinafter MEDPAC, MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM] [https://perma.cc/28TE-KZE7].

135. *See* Gellad & Hernandez, *supra* note 89, at 1503.

136. Inflation Reduction Act §11001 (codified as amended 42 U.S.C. § 1320f(a)(3)).

137. Juliette Cubanski, *FAQs About the Inflation Reduction Act's Medicare Drug Price Negotiation Program*, KFF (Jan. 31, 2024), https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program [https://perma.cc/VDD2-YZXY].

> (3) for Part B drugs, the payment under SSA Section 1847A(b)(4) for the 12-months prior.[138]

Importantly, the MFP determinations will not apply to all of Medicare's drug acquisitions. Instead, the Secretary must first determine an initial "list selected drugs" based on the top fifty highest-expenditure prescription drugs under Medicare Part B and Medicare Part D from the preceding year.[139] Eligibility for selection is additionally restricted by certain statutory limitations and exclusions.

For a drug to be considered "negotiation eligible," it must lack generic alternatives as a "single source drug," defined in Section I as either:

> (1) Approved under section 505I of the FDA Act and at least 7 years will have elapsed since the date of such approval and is not listed for generic approvals under 505(j) of such act; or
>
> (2) Biologic products that are "licensed under 351(a) of the Public Health Service Act" and "at least 11 years will have elapsed since the date of such licensure" and "not the reference product" for a biosimilar under 351(k) of such act.[140]

The drugs eligible for negotiations thus exclude a long list of potentially costly treatments, such as:

- Multiple source drugs (i.e., only single-source brand name drugs or biologics without approved generics or biosimilars, not including authorized generics, will be eligible for negotiation).
- Small molecule drugs will not be subject to negotiation unless they have been approved for at least nine years.
- Biological products will not be subject to negotiation unless they have been licensed for at least 13 years.
- Drugs that have received an "orphan drug" designation from the FDA for only one rare disease or condition and the only approved indication(s) is for such disease or condition.
- Low-spend Medicare drugs for which total spending under Medicare Parts B and D is less than $200 million in 2026 (increased by inflation in subsequent years).
- Biological products derived from human whole blood or plasma.

138. *See, e.g.*, Emily Jane Cook, Steven J. Schnelle, Tony Maida, Michael W. Ryan, Mary Moll Alexandre, Deepika Raj & Olivia Kaufmann, *CMS Issues Medicare Drug Price Negotiation Initial Guidance, First Inflation Rebate List*, MCDERMOTT, WILL, & EMERY (Apr. 4, 2023), https://www.mwe.com/insights/cms-issues-medicare-drug-price-negotiation-initial-guidance-first-inflation-rebate-list/ [https://perma.cc/MW97-BT89].

139. 42 U.S.C. § 1320f(a)(1); *see* Cubanski et al., *supra* note 16.

140. Inflation Reduction Act § 1192.

- Small biotech drugs for which total Part D or Part B spending for the drug during 2021 is equal to or less than 1% of total Part D/Part B spending for all drugs and is equal to at least 80% of total Part D/Part B spending for the manufacturer's drugs covered under Part D/Part B (only applies in 2026, 2027, and 2028). In 2029–2030, the MFP for small biotech drugs will not be subject to an MFP less than 34% off the non-FAMP.[141]

The Secretary began the selection process on August 29, 2023, choosing ten drugs covered under Medicare Part D for negotiations.[142] The actual "maximum fair price" agreements, however, will not become effective until 2026.[143] The ten selected drugs treat conditions ranging from diabetes (Farxiga) to psoriasis (Stelara), with the most expensive drug (Eliquis) costing Medicare more than $16 billion last year.[144] For drugs covered by Part B, implementation of MFP determinations will not occur until in 2028, with the Secretary initially selecting fifteen negotiation-eligible drugs.[145] The maximum fair price agreements of the selected drugs will become effective in 2028.[146] The Secretary is directed to increase the number of drugs selected for negotiation over time, potentially reaching 100 drugs by 2031.[147]

141. *See* Cubanski, *supra* note 137; *Summary of Medicare Drug Negotiation Program in Inflation Reduction Act and Impact on Pharmacies and Providers*, BASS, BERRY & SIMS (Aug. 12, 2022), https://www.bassberry.com/news/medicare-drug-negotiation-program-in-inflation-reduction-act/ [https://perma.cc/TPR9-AUYQ].

142. *See* Cubanski, *supra* note 137.

143. *See Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, CMS, https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf [https://perma.cc/X3FW-5V77] (last visited Mar. 19, 2024).

144. The ten selected drugs include: Eliquis (prevention and treatment of blood clots); Jardiance (diabetes and heart failure); Xarelto (prevention and treatment of blood clots and reduction of risk for patients with coronary or peripheral artery disease); Januvia (diabetes); Farxiga (diabetes, heart failure, and chronic kidney disease); Entresto (heart failure); Enbrel (rheumatoid arthritis, psoriasis, and psoriatic arthritis); Imbruvica (blood cancers); and Stelara (psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis). Cubanski, *supra* note 137; *HHS Selects the First Drugs for Medicare Drug Price Negotiation*, U.S. DEP'T HEALTH & HUM. SERVS. (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html [https://perma.cc/STB9-FP28]; *see* Amy Goldstein & Daniel Gilbert, *Biden Administration Names 10 Prescription Drugs for Price Negotiations*, WASH. POST (Aug. 29, 2023, 8:10 AM), https://www.washingtonpost.com/health/2023/08/29/medicare-drug-price-negotiations/ [https://perma.cc/2Q6C-77HV].

145. Cubanski, *supra* note 137.

146. *See id.*

147. *See id.*; *see also Updated Reconciliation Package Changes Drugs Eligible for Negotiation*, AVALERE (July 25, 2022), https://avalere.com/insights/updated-reconciliation-package-changes-drugs-eligible-for-negotiation [https://perma.cc/XE8M-CVGY].

d. Evaluation of MFP Reform

The Secretary's expanded authority to engage in MFP determinations could, at least theoretically, be an important stride in Medicare's use of value-based considerations in its drug purchases. The IRA's long-term impact on drug prices, however, will depend heavily on how pharmaceuticals respond to price controls.

Some have postulated that MFP controls may lower prescription drug costs for both Medicare and non-Medicare consumers.[148] Potentially, if buyers in the commercial market are privy to the lower, "fair" prices paid under Medicare, they may be afforded greater negotiating authority to demand similarly low drug costs.[149] Additionally, as discussed by Sarfaraz K. Niazi, in *The Inflation Reduction Act: A Boon for the Generic and Biosimilar Industry*, the selective eligibility for price-reductions should encourage competition in the prescription drug market, particularly for biologics.[150] Here, drug manufacturers may encourage or aid the entry of generics or biosimilars to avoid qualification for price reductions.[151]

Notwithstanding these potential price reductions, the net impact of MFP determinations on lowering prescription drug costs is dubious. Even if Medicare's fair pricing models bleed into the commercial market, these cost savings are likely to be capped by the fact that Medicare's newfound negotiating authority only applies to a select number of drugs. Here, the IRA imposes cost-reducing measures that, theoretically, will reduce industry participants' ability to charge Medicare excessive prices.[152] In practice, however, the small number of drugs eligible for MFP determinations in any given year and the lengthy list of exceptions to MFP eligibility will enable drug manufacturers to, in the long-term, strategically circumvent these future price controls.[153] As a result, even after the passage of the IRA, Medicare's control over its prescription drug purchases remains unduly restricted.

148. *See Brand Drug Launch Prices: A Game of Perspective*, 46BROOKLYN (Mar. 9, 2023), https://www.46brooklyn.com/research/3/9/2023/brand-launch-prices-revisited [https://perma.cc/9SJ7-88QB].

149. *See id.* (admitting that "whether the rest of the market, including forces outside of the manufacturer, will raise prices to address these new price concessions is something that could conceivably happen to blunt the impact of price negotiation").

150. *See* Sarfaraz K. Niazi, *The Inflation Reduction Act: A Boon for the Generic and Biosimilar Industry*, J. CLINICAL PHARMACY & THERAPEUTICS 1738, 1746–49 (2022).

151. *See id.*

152. *See id.*

153. *See* Cubanski, *supra* note 137.

Additionally, the Secretary's use of the markets-based metric "non-FAMP," or the non-federal, average manufacturing price for drugs sold to wholesalers,[154] for MFP determinations may be susceptible to manipulation by industry participants. Generally, a drug's non-FAMP is reflective of historical drug prices and should thus be indicative of a drug's fair value, as determined by other buyers in the market. Although a drug's non-FAMP includes adjustments, such as prompt pay discounts, it does not incorporate the potentially sizable discounts and rebates offered to Medicare insurance plans or PBMs.[155] As discussed later in this Article, drugmakers may attempt to raise MFP ceilings by artificially inflating prices used to calculate non-FAMP, and then selectively lower the costs for favored buyers through these excluded discounts. As a consequence, certain disfavored buyers, who do not obtain pricing concessions, may experience even greater drug price inflation. Additionally, the use of this market-based metric may increase the negotiating authority yielded by the PBM industry.

e. IRA Inflation-linked Price Controls

Like Medicare's newly granted negotiating authority, the IRA's inflation-based rebate provisions are likely to be an ineffectual weapon in the fight against escalating drug costs. Under the IRA, drug manufacturers are required to pay a rebate to the federal government if prices for certain drugs (single-source drugs and biologicals) covered under Medicare Part B, and nearly all covered drugs under Part D, increase faster than a measure of the rate of inflation known as the Consumer Price Index for All Urban Consumers ("CPI-U").[156] While in the short-term the IRA's inflation-linked rebates may prevent excessive cost

154. *See id*.

155. The non-FAMP does not include rebates paid by the drug's manufacturer to third parties such as insurance companies or PBMs. The non-FAMP is already used to calculate the Federal Ceiling Price ("FCP") for pharmaceutical purchases made by all direct federal purchasers, such as the Department of Veterans Affairs, the Department of Defense and the Public Health Service. CBO, COMPARISON OF BRAND-NAME DRUG PRICES, *supra* note 74, at 1; *see also* Sean D. Sullivan, *Medicare Drug Price Negotiation in the United States: Implications and Unanswered Questions*, 26 VALUE IN HEALTH 394, 395 (2023).

156. *See* Cubanski et al., *supra* note 16 (The rebate amount is equal to the total number of units sold in Medicare multiplied by the amount, if any, by which a drug's price in a given year exceeds the inflation-adjusted price. The base year for measuring cumulative price changes relative to inflation is 2021.).

increases on certain currently available treatments, in the long-term, manufacturers will likely be able to evade these pricing constraints.[157]

The IRA's attempt to control drug costs through the imposition of inflation-linked rebates detrimentally fails to permit Medicare to consider value-based metrics in its pricing determinations.[158] Instead, the IRA's inflation-linked rebates are based on market-based metrics that, as discussed later, risk manipulation by industry participants. In particular, the IRA's inflation-linked rebates will not prevent drug manufacturers from setting exorbitant prices at launch.[159] Accordingly, in order to avoid cost reductions related to inflation-linked rebates, drug manufacturers will simply shift their pricing strategies away from the current practice of gradual, year-over-year pricing increases, and instead aggregate these gradual price increases into the drug's price at the time of its entry to market.

By aggregating these gradual price increases into a drug's market price at launch, pharmaceuticals are likely to be able to maintain comparable levels of profitability notwithstanding the IRA's purported price controls. As Walid F. Gellad and Inmaculada Hernandez discuss in *Pharmaceutical Spending in Fee-for-Service Medicare: Looking Ahead to the Inflation Reduction Act*, not only does the IRA lack a mechanism to control exorbitant launch prices but could further "incentivize higher launch prices as an effort to offset slower growth in prices after launch."[160] As a result, absent additional authority to consider value-based metrics, Medicare may be incapable of redressing exorbitant drug costs if such price gouging is implemented at market launch. With the extended time-horizon until implementation of the rebate provisions—its effective date has been delayed until at least at least 2032[161]–pharmaceuticals will likely have sufficient time to engage in such long-term strategy shifts.

157. *Id*.; *see also* MEDPAC, MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM, *supra* note 134, at 107.

158. *See* Gellad & Hernandez, *supra* note 89, at 1503.

159. *See id.*

160. *Id*.

161. *See* DANA GOLDMAN, JOSEPH GROGAN, DARIUS LAKDAWALLA, BARRY LIDEN, JASON SHAFRIN, KYI-SIN THAN & ERIN TRISH, UNIV. S. CAL. SCHAEFFER CTR., MITIGATING THE INFLATION REDUCTION ACT'S ADVERSE IMPACTS ON THE PRESCRIPTION DRUG MARKET 4 (2023), https://healthpolicy.usc.edu/research/mitigating-the-inflation-reduction-acts-potential-adverse-impacts-on-the-prescription-drug-market/ [https://perma.cc/93AZ-6CZG].

The ability to circumvent inflation-linked rebates means that, even with the IRA's attempted reforms, Medicare's ability to impose cost-reducing measures is greatly restricted. Without the additional authority to forgo a drug purchase with a cost that is excessively high relative to the clinical benefit offered, Medicare remains susceptible to paying excessive drug costs. This risk is particularly high for new market entrants that are the first-in-class of a type of therapy, typically making Medicare coverage mandatory.[162] The long-term consequences of inflation-linked rebates therefore will result in very questionable cost-savings, for public and private payers alike.

Already, pharmaceuticals have begun to change their pricing strategies to launch drugs with exceedingly high price tags. While drug manufacturers once hesitated to bring drugs to market with price tags of over $5,000 per month, they have since abandoned their restraint, with monthly costs for many cancer drugs tipping towards $20,000, or around $240,000/year.[163] Other prices are even more astronomical. For example, the blood disorder treatment CSL Ltd Hemgenix was launched at an annual cost of $3.5 million.[164] This phenomenon is likely to become more pronounced for drugs brought to market in the post-IRA era.

Notably, the inflation rebates, which are already required for Medicaid drug purchases,[165] have been linked to the rise in launch prices of prescription drugs.[166] As stated in the Congressional Budget Office's 2022 Report, *Prescription Drugs: Spending, Use, and Prices*,

162. *See, e.g.*, MEDPAC, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 414 (2019), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar19_medpac_entirereport_sec_rev.pdf [https://perma.cc/6T2F-SG97].

163. For example, the cancer treatment Krazati was launched in December 2022 at $19,750 a month, along with Lumakras in 2021, which carried a monthly bill of $17,900. *See* Peter Loftus, *New Drugs for Cancer, Rare Disease Can Now Cost More Than $20,000 a Month*, WALL ST. J. (Mar. 9, 2023, 4:43 PM), https://www.wsj.com/articles/new-drugs-are-coming-to-market-at-sky-high-prices-4736372e?mod=hp_lead_pos7 [https://perma.cc/6NBS-YPW4].

164. *Id*.

165. Medicaid inflation rebates are based on the rate of increase in the AMP (average manufacturer price) relative to the CPI-U from a base period, which for each drug is either the quarter in which the drug entered the market or the quarter before the federal drug rebate program began, whichever is later. *See* CBO, COMPARISON OF BRAND-NAME DRUG PRICES, *supra* note 74, at 10.

166. *See id*. at 14 (stating that "[t]he inflation-based component of the Medicaid rebate discourages drug manufacturers from raising the AMP faster than the CPI-U once a drug is on the market," but "also encourages them to set higher prices for new drugs than they otherwise would").

"Medicaid's statutory rebates create an incentive for manufacturers to negotiate higher prices for commercial insurers as well as higher market wide launch prices."[167]

f. Potential Legal Challenges to IRA Reform

The failure to consider Medicare's prescription drug spending in the context of broader pharmaceutical policy objectives has additionally complicated efforts to reign in rapidly escalating drug costs. In particular, the patchwork system of regulation over the pharmaceutical industry has left the IRA's potential cost-controlling measures vulnerable to a host of legal challenges.[168] Several pharmaceutical companies, as well as the U.S. Chamber of Commerce, have already filed lawsuits challenging the IRA on multiple fronts.[169] Three of the most plausible of these arguments are as follows:

First, the IRA's price "negotiation" provisions arguably violate the Takings Clause, because there is no actual negotiation between drugmakers and Medicare. Instead, Medicare gives manufacturers a Hobson's choice of either selling a particular drug at an artificially low price unilaterally determined by Medicare or paying a prohibitive excise tax on every sale of the drug, starting at 186% of the drug's daily revenues and rising to 1900% of such revenues.[170] One litigant asserts:

> If a manufacturer refuses to "agree" to whatever HHS decides is the "maximum fair price," the manufacturer is hit with an "excise tax" penalty of up to 19 times the daily gross sales of the drug—all U.S. sales, not just sales in connection with government healthcare programs. This is no tax; it is more like an ax. Because no one could

167. CBO, PRESCRIPTION DRUGS, *supra* note 7, at 2 (stating that the increase in the overall share of the market that is covered by Medicare and Medicaid "may dampen the pressure on manufacturers to restrain prices because patients are more willing to purchase high-priced drugs when they have less exposure to those prices").

168. *See, e.g.*, Complaint at 6, Nat'l Infusion Ctr. v. Becerra, No. 1:23-cv-00707 (W. D. Tex. June 21, 2023) (claiming the IRA has "impermissibly delegated broad, unconstrained authority to HHS to set prices within Medicare," and violates First Amendment free speech rights, the Eighth Amendment's Excessive Fines Clause and the Fifth Amendment's Due Process Clause); Complaint at 3, Bristol Myers Squibb Co. v. Becerra, No. 3:23-cv-03335 (D. N. J. June 16, 2023) (claiming that the IRA effects an unconstitutional taking of private property without just compensation).

169. Nyah Phengsitthy, *Major Drugmakers Team Up in Court Against Price Negotiations*, BL (Mar. 6, 2024, 10:29 AM), https://news.bloomberglaw.com/health-law-and-business/major-drugmakers-to-join-forces-in-court-for-drug-pricing-battle [https://perma.cc/HH9A-8A4D].

170. Complaint of Nat'l Infusion Ctr., *supra* note 168, at 38.

> afford to pay such an exorbitant penalty, the purported "tax" is in reality an ultimatum to pharmaceutical companies: "agree" to whatever price the government names, or we'll smash up your business.[171]

According to drug manufacturers, by using the threat of prohibitively high penalties, the government will force a drugmaker to provide Medicare with a drug for a fraction of its value, thereby affecting an unconstitutional taking of private property without just compensation.

Second, the IRA's negotiation provisions arguably violate First Amendment guarantees by requiring a manufacturer who wishes to sell drugs to Medicare to sign a "Manufacturer's Agreement," which contains a provision stating that the drug price unilaterally set by Medicare is a "fair" price for the drug.[172] Further, the IRA requires manufacturers of drugs selected for price negotiations to submit detailed and highly confidential business information to CMS or face draconian fines.[173]

Third, the IRA arguably offends fundamental notions of due process because it gives HHS virtually unfettered discretion to set drug prices and to impose confiscatory penalties without any meaningful judicial oversight. While Congress provided a list of "factors" that HHS should consider when setting a "fair" drug price,[174] CMS has acknowledged that the IRA "does not specify how CMS should determine an initial offer [on price] nor how or to what degree each factor should be considered."[175] Importantly, moreover, the IRA specifically bars administrative and judicial review of many of the key aspects of the price negotiation program, including the drugs that are selected for "negotiation" and the "maximum fair prices" set by the agency.[176] Litigants reasonably complain that their due process rights are violated by the IRA's negotiation scheme because Congress not only failed to legislate

171. Complaint at 5–6, Dayton Area Chamber Com. v. Becerra, No. 3:23-cv-00156-TMR-PBS (S.D. Ohio June 9, 2023).

172. *See* CENT. FOR MEDICARE & MEDICAID SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: REVISED GUIDANCE 32 (2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-guidance-june-2023.pdf [https://perma.cc/3RGF-7C6Z].

173. *See* 42 U.S.C. § 1302f(d)(5)(A).

174. *Id*. § 1320f-3(e).

175. *See* CENT. FOR MEDICARE & MEDICAID SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: INITIAL MEMORANDUM 1, 34–47 (2023), https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf [https://perma.cc/D44W-BDWA].

176. 42 U.S.C. § 1320f-7.

any standards for setting drug prices but also barred judicial review of the Secretary's key decisions on drug selection and pricing.[177]

PART III: THE SECONDARY CONSEQUENCES OF MEDICARE'S PRESCRIPTION DRUG POLICY

In light of the statutory limitations discussed above, which limit Medicare's negotiating authority and preclude the use of value-based considerations, Medicare is forced to maintain a largely passive role in the pricing determinations of its prescription drug purchases. Limitations on Medicare's pricing authority, however, have led to a host of unintended consequences on the prescription drug market. In particular, three aspects of Medicare's purchasing program have contributed to price inflation across the prescription drug market.

First, due to restrictions on the use of value-based considerations, Medicare must rely heavily on market-based pricing metrics, such as the average sales price ("ASP"), in its drug acquisitions.[178] Such metrics, however, may be artificially inflated by industry participants, leading to increased costs across buyers in the market.

Second, in order to avoid direct participation in the marketplace, Medicare often must utilize third-party intermediaries for drug pricing negotiations and coverage determinations.[179] In certain instances, perverse financial incentives encourage Medicare intermediaries to favor treatment options with the highest cost to Medicare, notwithstanding the existence of less expensive—and, at times, more effective—treatment options.

Third, Medicare policy has inadvertently influenced certain types of pharmaceutical research and drug development spending, shifting innovation towards the development of treatments where Medicare's negotiating authority is weakest to maximize potential for profitability.[180]

177. *See* Complaint of Dayton Area Chamber of Commerce, *supra* note 171, at 45–46.
178. *See* Hemel & Oullette, *Valuing Medical Innovation*, *supra* note 12, at 539–40.
179. *Id.* at 541–43.
180. *Id.* at 517.

A. Reimbursement for Prescription Drug Costs Using ASP

Even after the passage of the IRA, Medicare's ability to engage in pricing negotiations for Part B-covered drugs remains heavily restricted.[181] Rather than engage in an independent assessment of a drug's fair value, Medicare, under Part B, makes pricing determinations using a pre-determined formula that incorporates an average of the "prices" paid by other buyers in the market.[182] More specifically, Medicare determines the prices of drugs covered under Part B by reimbursing healthcare providers at 104.3% of the ASP.[183] Medicare's use of ASP not only leaves it susceptible to paying for inflated drug prices, but also risks inflating drug prices for other purchasers in the market.[184]

1. ASP REIMBURSEMENT METHODOLOGY

A drug's ASP is calculated by taking a weighted average of sales price data that CMS collects from drug manufacturers on a quarterly period.[185] Theoretically, a drug's ASP should thus be representative of a drug's fair price, as determined by other non-Medicare purchasers. In many instances, however, describing this metric as the "average sales price" is a bit of a misnomer. As discussed earlier, the prescription drug market is wrought with highly variable pricing schemes, driven by the different rebates and price discounts afforded to those with disparate purchasing power. Furthermore, even if buyers were offered uniform prices, there is no guarantee that these prices would be *fair*. A number of factors, such as buyers' inelastic demand curves and sellers' monopolistic market control, undermine market efficiency, weakening the link between market prices and fair value. As a result, not only is

181. As will be discussed more fully below, beginning this year most Part B drugs will be subject to the IRA's inflation-linked rebate provisions. *See infra* Part III.A.2.a.

182. *See* Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 12, at 539–40.

183. *Id.*

184. Medicare normally must reimburse providers for 106% of ASP, but from July 1, 2022 through June 30, 2031, Medicare will reimburse under Part B at 104.3% of ASP. *See id.*; *see also* Cubanski et al., *supra* note 16.

185. More specifically, ASP is the price paid to drug manufacturers from all U.S. purchasers in a calendar quarter, excluding sales to certain federal and state purchasers, and net of certain rebates and discounts. *See* Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 12, at 539–40.

determining the actual average cost of a prescription drugs exceedingly difficult, but also likely a poor representation of fair value.[186]

Additionally, the formulaic reimbursement methodology used in Part B hinders Medicare's discretion to correct for these inefficiencies by precluding Medicare from incorporating discretionary factors, such as improvement in health outcomes or quality of life, into its purchasing determinations.[187] Instead, under Part B, Medicare is generally bound to accept the result of ASP calculations. Here, a drug manufacturer with a patent-protected drug product may be able to make Medicare a "price-taker,"[188] effectively setting its own Medicare payment rate by inflating the market prices that make up the drug's ASP.[189] Accordingly, Medicare's mandatory use of ASP to establish drug prices not only prevents it from engaging in its own fair value assessment, but also leaves its pricing determinations vulnerable to manipulation by industry participants.

2. IMPACT ON PRESCRIPTION DRUG COSTS

Medicare's inability to correct for pricing inefficiencies has contributed to the dramatic increase in the average prices of the types of treatments covered under Part B.[190] This financial burden has not only impacted Medicare's costs, which under Part B have grown substantially, but also the prices paid by individual patients in need of medicine.[191] As the MedPAC's 2022 report states, "[t]he prices Medicare pays

186. *See, e.g.*, Sarosh Nagar, Leah Z. Rand & Aaron S. Kesselheim, *What Should US Policymakers Learn From International Drug Pricing Transparency Strategies*?, 24 AMA J. ETHICS. 1083, 1086–87 (2022).

187. SHEINGOLD ET AL., *supra* note 86, at 7.

188. *See, e.g.*, Anna Kaltenboeck, *As US Begins to Tackle High Drug Prices, Congress Gets in the Way*, BL (Mar. 23, 2023, 3:00 AM) https://news.bloomberglaw.com/us-law-week/as-us-begins-to-tackle-high-drug-prices-congress-gets-in-the-way [https://perma.cc/4FWZ-BHZH] (describing Medicare as having a "historic role as a price taker in a market where price makers—pharmaceutical manufacturers, that is—have had overwhelming advantages in determining what one of the nation's largest payers pays for prescription drugs").

189. MEDPAC, MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM, *supra* note 134, at 84.

190. Alvaro San-Juan-Rodriguez, Walid F. Gellad, William H. Shrank, Chester B. Good, & Inmaculada Hernandez, *A Decade of Increases in Medicare Part B Pharmaceutical Spending: What Are the Drivers?*, 27 J. MANAGED CARE & SPECIALTY PHARMACY 565, 568 (2021).

191. MEDPAC, MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM, *supra* note 134, at 21 (stating that in 2020 private consumers' costs for hospital-administered drugs was more than double the prices paid for non-Part B drugs, such as Medicare's Fee-for-Service program).

for drugs are an important driver of this growth," given that Medicare "has had only an indirect influence on how new Part B-covered drugs are priced."[192] Furthermore, while Medicare Part D is the greatest source of prescription drug spending costs, virtually all of the drug spending increase has been derived from Part-B-covered drugs.[193] The profitability of this arrangement is also apparent in the discrepancies between Medicare's share of prescription drug spending on non-retail drugs, such as those administered in hospitals and other in-patient centers, and the national average spending.[194] Notably, the national average spending on non-retail drugs is 30% of overall prescription drug costs, whereas Medicare's reaches 50%.[195]

In addition to undermining Medicare's financial sustainability, this formulaic pricing model can also raise costs for many Medicare beneficiaries. For Part B-covered drugs, beneficiaries are often subject to a coinsurance obligation, or financial responsibility based on a percentage of the drug's price.[196] Furthermore, the $2,000 out-of-pocket limitation set forth by the IRA in Part D does not apply to Part B-covered services, leaving those covered by Part B subject to substantial potential financial liability.[197]

a. Private Market Price Inflation

Price inflation caused by Part B's reimbursement methodology, however, is not limited to only Medicare's purchases. As stated by Hemel and Ouellette, linking Medicare's pricing and reimbursement

192. *Id.* at xiv.
193. *See id*.
194. *See* Michael Cohen & Tamara Hayford, A *Discussion of Recent Research on Health Care Prices: Prescription Drugs, Hospitals' Services, and Physicians' Services*, CONG. BUDGET OFF. (Apr. 27, 2022), https://www.cbo.gov/publication/58026 [https://perma.cc/J9ET-22YZ].
195. ASPE, TRENDS IN PRESCRIPTION DRUG SPENDING 2016–2021 2 (2022), https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf [https://perma.cc/N6MJ-UDR7].
196. *See* Diane Omdahl, *Medicare's Out-Of-Pocket Maximum Limit: How Much Will It Cost You?*, FORBES (July 14, 2020), https://www.forbes.com/sites/dianeomdahl/2023/09/12/how-much-will-your-free-medicare-advantage-plan-really-cost/# [https://perma.cc/D8UE-ST2Q].
197. Juliette Cubanski & Tricia Neuman, *Changes to Medicare Part D in 2024 and 2025 Under the Inflation Reduction Act and How Enrollees Will Benefit*, KFF (Apr. 20, 2023), https://www.kff.org/medicare/issue-brief/changes-to-medicare-part-d-in-2024-and-2025-under-the-inflation-reduction-act-and-how-enrollees-will-benefit/ [https://perma.cc/4FKD-ECDP].

methodology to the average prices paid by private market purchasers "causes firms to raise prices for non-government payers so they can extract larger sums from Medicare."[198] Drug manufacturers, knowing that one of their largest purchasers, Medicare, will be bound to the formulaic calculation of ASP, may seek to maximize their profitability by inflating the market averages used to calculate this reimbursement rate.

Accordingly, as an "unintended side effect" of Medicare reimbursement under Part B, drug manufacturers may be financially incentivized to raise drug prices for non-Medicare purchasers of prescription drugs in order to increase the average sales prices used under Part B's reimbursement methodology.[199] Although some in the market with strong negotiating authority may be able to evade inflated market prices, many are not so lucky. Unfavored buyers, such as those with weak or no insurance coverage, are often left bearing the harsh consequences of artificially inflated drug prices, forcing such individuals to pay crippling costs for physician-administered treatments.[200]

B. Medicare's Reliance on Third-party Intermediaries

The IRA additionally fails to address Medicare's mandated reliance on third-party intermediaries for certain drug purchasing and coverage determinations. Without adequate control over these determinations, Medicare is often unable to address the effect of misaligned incentive structures, which can encourage intermediaries to select the highest costing treatments, even when less expensive—and, at times, more effective—treatment options exist. Discussed below are the secondary consequences of Medicare's use of private intermediaries for drugs covered under Part B and Part D of the program.

1. "REASONABLE AND NECESSARY" DETERMINATIONS UNDER PART B

In addition to relying on the market-based metric, ASP, to reimburse providers in lieu of making its own value-based pricing determinations, Medicare, under Part B, also forgoes making its own coverage decisions and instead relies largely on drug administrators to make such determinations.[201]

198. *See* Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 12, at 517.
199. *See* Weidner et al., *supra* note 51, at 156.
200. *See* Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 12, at 520–24.
201. *Id.* at 539–42.

Under Part B, Medicare will reimburse hospitals or physicians administering treatments if such treatments meet Part B coverage criteria as "reasonable and necessary for the diagnosis or treatment of illness or injury" or "for the prevention of illness."[202] After this criterion has been satisfied, healthcare providers will automatically receive 104.3% of the average sales price ("ASP") for such drugs or treatments.[203] To determine if a drug is "reasonable and necessary," CMS relies on a number of factors stated in its prescribed guidelines.[204] Here, Medicare considers a drug "reasonable and necessary" if the drug is, among other factors, "[f]urnished in accordance with accepted standards of medical practice" and "meets, but does not exceed, the patient's medical need," and is "[a]t least as beneficial as an existing and available medically appropriate alternative."[205]

While CMS theoretically may consider these factors, in practice whether a drug is deemed "reasonable and necessary" depends predominately on determinations made by the hospital or physician administering the treatment. At first glance, Medicare's deference to the determinations of the administering hospitals and physicians appears warranted, especially considering these providers' specialized medical knowledge. Closer examination, however, reveals that these third parties are highly susceptible to perverse financial incentives, as discussed below.

a. Reimbursement Methodology Under Part B is Divorced From the Actual Cost to the Drug Administrator

As mentioned earlier, under Part B, Medicare has historically provided drug administrators with reimbursement at the drug's ASP, plus an additional 4.3 percent (6 percent starting in 2031), regardless of the administrator's actual cost to obtain the drug or treatment.[206] Accordingly, increases in a drug's ASP also increases the actual value of the 4.3% fee earned by the physicians and hospitals administering the drug.

202. 42 U.S.C. § 1395y(a)(1)(A)-(B).

203. Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 12, at 539.

204. *See* Jacqueline LaPointe, *CMS Defines "Reasonable and Necessary" Medicare Coverage*, RECYCLE INTEL. (Jan. 15, 2021), https://revcycleintelligence.com/news/cms-defines-reasonable-and-necessary-medicare-coverage [https://perma.cc/FDK6-UEMN].

205. *Id.*

206. The 6% is provided to cover expenses related to physician-administered drugs. *See* Weidner et al., *supra* note 51.

(For example, 4.3% of a drug that costs $100 would earn a fee of $4.30 but 4.3% of a drug that costs $10,000 would earn a fee of $430.)[207] As a result, hospitals and administrating physicians often face a financial disincentive to negotiate for lower-cost treatment options, as lower-cost treatments entail lower reimbursement rates. Instead, drug administrators frequently stand to reap the greatest financial reward by administering treatments that have the highest costs to Medicare.

Furthermore, reimbursement at 104.3% of ASP regardless of administrators' actual costs in acquiring these treatments can create valuable arbitrage opportunities, especially where administrators have access to the drug substantially below the average market rate. Here, administering hospitals and out-patient centers can skim the greatest profit by purchasing their drugs at substantially lower prices than their reimbursement rate from Medicare. These providers thus have dual incentives to raise the average sales prices paid by all consumers: inflated ASP values both maximize the 4.3% fee earned and increase the spread between drug cost and reimbursement.[208]

b. Section 340B Hospitals

The profitability offered by the discrepancies between drug costs and Medicare reimbursement rates is particularly pronounced in the case of Section 340B Hospitals, which, under the 340B Drug Pricing Program, enables hospitals qualifying as serving a "high need population"[209] to negotiate for discounted drug prices to serve their in-need populations.[210] The size of discounts afforded to 340B hospitals can be

207. For a more realistic example of pricing incentives, *see* Sham Mailankody & Vinay Prasad, *Implications of Proposed Medicare Reforms to Counteract High Cancer Drug Price*s, 316 J. AM. MED. ASS'N 271 (2016).

208. *See* Weidner et al., *supra* note 51 at 157–58.

209. To qualify under as a Section 340B Hospital, a hospital must meet criteria for serving a high-need population, including low-income and uninsured patients, at locations such as rural or community hospitals. *See* AM. HOSP. ASS'N, FACT SHEET: THE 340B DRUG PRICING PROGRAM 1–2 (2023), https://www.aha.org/system/files/media/file/2019/03/fact-sheet-340b-drug-pricinig-program-0119.pdf [https://perma.cc/N9EG-YV4T].

210. Section 340B-eligible hospitals must, among other things, be owned by a state or local government, be a public or private non-profit corporation that a state or local government has granted governmental powers or be a private non-profit hospital with a contract with a state or local government to provide health care services to low-income individuals not covered by Medicaid or Medicare. *See id*.

significant, ranging from 25% to 50% of drug costs.[211] While 340B hospitals can demand lower drug prices from manufacturers, they are not obligated to deliver such discounted prices to the program's intended low-income or uninsured beneficiaries. Instead, these hospitals can acquire drugs at the discounted 340B rate but then deliver these therapies to *Medicare* beneficiaries, resulting in reimbursement by the government at 104.3% of ASP.[212]

In 2018, CMS attempted to remedy this issue by reimbursing outpatient drugs purchased under the 340B program at ASP *minus* 22.5%.[213] Recently, however, in *American Hospital Ass'n v. Becerra*, the Supreme Court declared the reimbursement rate change as "contrary to the statute and unlawful."[214] Notably, the amendments enacted under the IRA do not address providers' ability to acquire drugs at 340B prices while receiving reimbursement at higher Medicare pricing rates.

c. Potential Influence on Quality of Care

Additionally, with such significant reliance on third-party providers to determine what treatment is "reasonable and necessary," Medicare forgoes conducting its own analysis of important value-based factors, such as comparative effectiveness of treatment or additional clinical benefit provided relative to price, in its purchasing determinations. Instead, the drug must only prove to be "[a]t least as beneficial as an existing and available medically appropriate alternative," regardless of whether other, less expensive alternatives exist with comparable clinical benefit.[215] Without the discretion to compare relative value or benefit conferred by drug options, CMS is severely limited in its ability to not only constrain its own costs, but also to ensure that a beneficiary

211. Bobby Clark & Marlene Sneha Puthiyath, *The Federal 340B Drug Pricing Program: What It Is, and Why It's Facing Legal Challenges*, COMMONWEALTH FUND (Sept. 8, 2022), https://www.commonwealthfund.org/publications/explainer/2022/sep/federal-340b-drug-pricing-program-what-it-is-why-its-facing-legal-challenges [https://perma.cc/5J7T-F9T7].

212. *Id. See* Stephen Barlas, *CMS Finalizes Drastic 340B Reimbursement Cut for 2018*, 43(1) PHARMACY AND THERAPEUTICS 12, 12 (2018).

213. *See Hospital Outpatient Prospective Payment System (OPPS): Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 Final Rule (CMS 1793-F)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 2, 2023), https://www.cms.gov/newsroom/fact-sheets/hospital-outpatient-prospective-payment-system-opps-remedy-340b-acquired-drug-payment-policy [https://perma.cc/L468-W2V5].

214. Am. Hosp. Ass'n. v. Becerra, 596 U.S. 724, 739 (2022).

215. *See* LaPointe, *supra* note 204.

is administered treatment based on its potential efficacy, not its potential profitability.[216] This arrangement differs significantly from other countries, where, as discussed previously, entities evaluate the clinical value offered by a drug or treatment before reaching a purchase agreement.[217]

2. THE USE OF PRIVATE INTERMEDIARIES UNDER MEDICARE PART D

The IRA additionally fails to lift the statutory constraints governing Part D, which prohibit Medicare's direct participation in the prescription drug market. As discussed, the Part D program substantially expanded Medicare's coverage of its beneficiaries' prescription drug costs. Due to the limitations imposed under the MMA, however, the Part D program cannot directly serve as an insurer to its beneficiaries. Instead, the Part D program[218] subsidizes access to certain private insurance plans, known as plan sponsors, for coverage of prescription drug costs.[219] As part of their contractual arrangement, plan sponsors negotiate on behalf of Medicare with other intermediaries along the pharmaceutical supply chain.[220] While the use of private-market intermediaries was intended to minimize Medicare's disruption to "free-market forces," the requirement has inadvertently contributed to pricing inefficiencies and distorted market incentives. Specifically, Medicare's reliance on intermediaries may impose needless additional costs or, even worse, create perverse financial incentives that are inapposite of reducing Medicare's costs.

a. Additional Costs Incurred by Use of Intermediaries

By contracting out its negotiation processes under Part D, Medicare risks incurring superfluous costs by the use of "middlemen," which must also be compensated.[221] As stated by Jonathan Oberlander,

216. *See id*.
217. *See supra* Part I.B.1.
218. *See* Shilling, *supra* note 108, at 1.
219. KKF, *Medicare Part D*, *supra* note 93; *see also* O'Brien, *supra* note 108.
220. *See supra* Part II.B.1.
221. *See* Kathryn Judge, *From Meat to Insulin, How the Middlemen Economy Makes Everything More Expensive*, TIME (Aug. 23, 2022, 7:00 AM), https://time.com/6207701/us-economy-middlemen-prices/ [https://perma.cc/WNG9-RKXC] (stating that similar to many middlemen, pharmaceutical intermediaries, such as PBMs, originally started out providing value by "facilitating the flow of payments and

in *Medicare for All—Running Down a Dream*, "[m]uch of what Americans spend on medical care actually pays for the staggering administrative costs generated by our complex insurance arrangements"[222] These extraneous costs play a critical role in determining the cost of prescription drugs, making them a key driver of the relatively higher drug costs and medical services in the United States.[223]

b. Misaligned Incentives

In addition to the significant costs associated with intermediaries in the prescription drug supply chain, Medicare may be relying on intermediaries that have competing financial incentives. In theory, the shared obligation of Medicare and plan sponsors to provide affordable prescription medication should align their interests in negotiating for lower drug costs. In practice, however, plan sponsors must additionally engage in negotiations with various actors along the pharmaceutical supply chain, such as PBMs and dispensing pharmacies. Accordingly, while Medicare only directly contracts with plan sponsors, its prescription drug costs are additionally dependent on these third parties, which often stand to reap the greatest profitability by maximizing Medicare's costs. Here, Medicare's dependency on third-party intermediaries leaves it vulnerable to pricing manipulation by those with misaligned financial incentives. Thus, efforts to preserve market efficiency by limiting Medicare's direct participation in the prescription drug market, have ironically exacerbated price distortions and inefficiencies in that market.[224]

C. The Role of PBMs in Part D Drug Purchases

Importantly, Medicare's mandated use of plan sponsors under Part D has indirectly contributed to the growing authority of PBMs in the prescription drug market. Both private-market insurers and Medicare's plan sponsors contract with PBMs to manage their prescription

otherwise serving as a helpful bridge between insurers and drug companies," but eventually began to extract more value than they contributed once given the opportunity).

222. Jonathan Oberlander, *Medicare for All–Running Down a Dream*, 48 J. HEALTH POL., POL'Y & L. 435, 437.

223. *Id.*

224. *See* Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2314–15 (2018).

drug purchases and engage in negotiations with drug manufactures and dispensing pharmacies for pricing concessions.[225] As part of this process, PBMs make pivotal determinations about a drug's level of coverage on insurance plans, otherwise known as a drug's formulary placement.[226] This means that PBMs ultimately determine which drugs will receive the highest reimbursement amounts from the insurance provider, which in turn, determines which drugs are adopted by patients (as favorable formulary placement entails lower out-of-pocket costs and thus greater adoption rates by patients). Accordingly, PBMs' formulary determinations play a pivotal role in driving drug sales, making them a highly influential intermediary in the pharmaceutical supply chain.[227] Furthermore, PBMs' indirect control of Medicare's billions in spending decisions has only bolstered their market authority, enabling them to demand greater pricing concessions during the negotiation process. While the pricing concessions obtained by PBMs often flow to insurers to help reduce costs, PBMs also pocket a portion of these various rebates and fees as a critical source of profitability.[228] Without adequate safeguards, PBMs' compensation structure can lead to perverse financial incentives that have become an important driver of drug price inflation for Medicare as well as non-Medicare drug purchases. A number of these warped financial incentives are discussed below.

1. PBM COMPENSATION STRUCTURE

a. Linking compensation to average market prices

Firstly, PBMs' compensation is often linked to the list price of the drugs they manage.[229] In a complicated process, PBMs earn "retained

225. PBMs earn income from the administrative fees charged for their services, as well as by keeping portions on the rebates and discounts that are negotiated with drug manufacturers. *See* NAIC, *supra* note 54.

226. *Id.*

227. Katherine Kennedy, *The Hidden System of Legal Kickbacks Shaping the U.S. Prescription Drug Market*, GLOB. ANTICORRUPTION BLOG (Feb. 27, 2023), https://globalanticorruptionblog.com/2023/02/27/the-hidden-system-of-legal-kickbacks-shaping-the-u-s-prescription-drug-market/ [https://perma.cc/FB86-FJL6].

228. *Id.*

229. PBM ACCOUNTABILITY PROJECT, UNDERSTANDING THE EVOLVING BUSINESS MODELS AND REVENUE OF PHARMACY BENEFIT MANAGERS 15 (2021), https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf

rebates" from drug manufacturers in order to incentivize PBMs to give their drug products favorable formulary placement on beneficiaries' insurance plans.[230] The size of these rebates is typically determined by taking a percentage of the drugs' average market price, or wholesale acquisition cost ("WAC"). Accordingly, the higher the list price of a drug, the larger the likely value of the retained rebate or fee earned by the PBM.[231] Like the reimbursement methodology under Part B, where providers' compensation is calculated as a percentage of ASP, the link between PBM compensation and average market prices also has the potential to create warped incentive structures—where PBMs' financial rewards increase as average drug prices rise. As a result, PBMs may be incentivized to give more favorable formulary treatment to more expensive drugs, as these yield them larger rebates.

Without active participation in the negotiations process, Medicare is left vulnerable to accepting deals that maximize PBM profitability by raising Medicare's costs. In fact, a 2016 study found that 72% of Medicare Part D plans favored at least one higher-cost brand medicine over an equivalent, cheaper generic product.[232] While PBMs often tout that they retain less than 1% of Medicare rebates,[233] the absolute value of this "1%" of retained rebates has steadily increased as drug prices have climbed. For example, rebates retained from Medicare Part D purchases increased from an estimated $12.7 billion in 2013 to a whopping $45.0 billion in 2020.[234]

Theoretically, PBMs are supposed to translate these rebates into lower drug costs. Under current law, however, PBMs are not legally obligated to do so, making these rebates a valuable source of profitability, especially in negotiations for private insurance plans.[235] Even where rebates are passed on to insurance providers, PBMs are financially disincentivized from lowering the *average* prices yielded by the market. As

[hereinafter PBM ACCOUNTABILITY PROJECT] [https://perma.cc/6UZH-YJ3P] (stating that "[s]everal sources of PBM revenue for medicines are linked directly to the list price of the medicine").

230. *Id*. at 11–12.

231. *Id*. at 15.

232. *Id*.

233. *See* Susan Morse, *Pharmacy Benefit Managers Keep Less Than 1% Percent of Rebates for Medicare Part D Drugs, GAO Says*, HEALTHCARE FIN. (Aug 14, 2019), https://www.healthcarefinancenews.com/news/pharmacy-benefit-managers-keep-less-1-percent-rebates-medicare-part-d-drugs-says-gao-report [https://perma.cc/73C2-JGZJ].

234. PBM ACCOUNTABILITY PROJECT, *supra* note 229, at 11.

235. *See id*. at 11–12.

a result, those without large PBMs negotiating on their behalf bear the brunt of the costs of the warped incentives offered to intermediaries to keep average market prices high.[236]

b. Additional Forms of Compensation

Furthermore, while Part D plan sponsors are required to report retained rebates to CMS, they are not required to report the payments they receive from drug manufacturers if earmarked as "administrative" or "service" fees, which are said to compensate for a variety of services such as drug utilization management, medical education, and data collection.[237] While drug manufacturers are only permitted to provide PBMs administrative fees as compensation for "bona fide services" at fair market value, the amount and nature of this compensation is typically kept confidential, even from insurance providers.[238] As stated by the Inspector General of HHS, if administrative fees paid by drug manufacturers relate to a drug's list price or the PBMs sales volume, "these fees could function as a disguised kickback."[239] As a result, the increasing amount of compensation awarded to PBMs as administrative "fees" has become an opaque form of PBM compensation capable of evading CMS reporting requirements.[240]

PBMs also charge pharmacies "clawbacks,"[241] or a portion of the direct and indirect remuneration ("DIR") that pharmacies provide to plan sponsors (which is estimated to be 18% of DIR paid to Part D

236. *Id*. at 15.

237. *Id.* at 12, 15.

238. U.S, DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN. OIG., OEI-02-08-00050, CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM 4 n.16 (2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf [https://perma.cc/V2SJ-S4FT].

239. CHARLES E. GRASSLEY & RON WYDEN, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG, S. REP. NO. 116-51, at 73 (2021).

240. *Id.* Federal regulations prohibit the release of PBM compensation information shared with CMS and private market information is generally kept confidential. However, CMS may "disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug." 42 U.S.C. 1396r-8(b)(3)(D) (cross-referenced at 42 U.S.C. 1395w-102(d)(2) & 1396r-8(b)(3)(D)).

241. *See* True N. Pol. Sols., *White Paper: DIR Fees Simply Explained*, PHARMACY TIMES (Oct. 25, 2017), https://www.pharmacytimes.com/view/white-paper-dir-fees-simply-explained [https://perma.cc/2VWG-KHFV]. "Clawbacks" are fees PBMs charge to pharmacies after the point-of-sale.

plans).[242] Because "clawbacks" generally go unreported, CMS is typically unaware of the frequently large payments taken by PBMs from pharmacies after Part D purchases.[243] The growing strain of "clawbacks" on pharmacies will likely become exacerbated should PBMs gain greater influence over the pharmaceutical market.[244]

2. THE IMPACT OF PART D ON PRIVATE MARKET PURCHASERS

An additional (yet infrequently discussed) consequence of the design of Part D has been its contribution to the growing influence of PBMs over prescription drug costs for *private* purchasers. Due to consolidation of the PBM industry, three of the largest PBMs, CVS Health, Express Scripts, and OptumRx (UnitedHealth) cover over 70% of prescriptions filled in the United States.[245] Accordingly, PBMs acting on behalf of insurers in the private markets are very likely to be the same PBMs involved with Part D sponsored plans and the related flow of Medicare spending.

While Medicare may restrict the amount of retained rebates collected by PBMs and impose reporting obligations for its own prescriptions, Medicare cannot control the rebates and fees charged by PBMs in *private-market* drug purchases. Accordingly, drug manufacturers, seeking to gain PBMs' influence over Medicare's coverage determinations (which, as noted previously, represent roughly 40% of the prescription drug market),[246] may channel a type of "back door" compensation to

242. *See id.*; *see also* Adam J. Fein, *Pharmacy DIR Fees Hit a Record $9 Billion in 2019—That's 18% of Total Medicare Part D Rebates*, DRUG CHANNELS (Feb. 13, 2020), https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.html [https://perma.cc/VP7H-X6V9]. CMS explains "DIR" as follows:

> Often, the Part D sponsor or its pharmacy benefits manager (PBM) receives additional compensation after the point-of-sale that serves to change the final cost of the drug for the payer, or the price paid to the pharmacy for the drug. Examples of such compensation include rebates provided by manufacturers and concessions paid by pharmacies. Under Medicare Part D, this post point-of-sale compensation is called Direct and Indirect Remuneration (DIR) and is factored into CMS' calculation of final Medicare payments to Part D plans.

Medicare Part D—Direct and Indirect Remuneration (DIR), CMS.GOV (Jan. 19, 2017), https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir [https://perma.cc/5NN4-NAR5].

243. True N. Pol. Sols., *supra* note 241.

244. *See* Fein, *supra* note 242.

245. CBO, PRESCRIPTION DRUGS, *supra* note 7, at 21.

246. *See supra* Part I.C.3.; *see also* KATHERINE KEISLER-STARKEY & LISA N. BUNCH, U.S. CENSUS BUREAU, NO. P60-278, HEALTH INSURANCE COVERAGE IN THE UNITED

the PBMs by paying PBMs hefty administrative "fees" or other pricing concessions during negotiations for their *non-Medicare* purchases.

PBMs' influence over Part D purchases has thus bestowed these intermediaries with potent market authority, across both public and private drug markets. As a result, PBMs yield tremendous leverage to make demands for fees and rebates, which have contributed to both growing PBM profitability—and rising prescription drug prices. The scope of these forms of "backdoor" compensation, however, is largely concealed due to the opacity of private market negotiations.[247] As a result, Medicare's reliance on private intermediaries has imposed secondary consequences on the prices paid by private market participants that are not reflected in data reported to CMS.

3. THE IMPACT OF THE IRA ON THE PBM INDUSTRY

a. Circumvention of Price Controls

The IRA's newly enacted price controls are likely to exacerbate the market influence of PBMs. Here, the complex system of rebates and fees collected by PBMs serves as a critical avenue to circumvent the IRA's efforts to lower prescription drug costs. By working with PBMs, drug manufacturers will be able to inflate the average market prices used to calculate Medicare reimbursement rates while selectively lowering costs for other buyers.

For example, if drug manufacturers respond to the IRA's inflation-linked rebates by increasing average launch prices of new drugs, PBMs can selectively negotiate price reductions through their complex web of "backdoor" rebates and administrative fees. These backdoor channels will become all the more critical to maintain competitive pricing for favored buyers while still maintaining inflated list prices. Additionally, certain PBM rebates are not included in the calculation of non-FAMP, which, as noted previously, is used in the IRA's recently enacted

STATES: 2021 2 (2022), https://www.census.gov/content/dam/Census/library/publications/2022/demo/p60-278.pdf [https://perma.cc/Y27X-6YLV].

247. Notably, however, the sheer profitability of the PBM industry has continued to rise. Between 2017 and 2019, PBM gross profit increased by 12%, from $25 billion to $28 billion. *See New Report Shows Pharmacy Benefit Managers Are Increasing Costs for Patients and the Health Care System*, BUS. WIRE (Dec. 2, 2021, 9:21 AM), https://www.businesswire.com/news/home/20211202005623/en/New-Report-Shows-Pharmacy-Benefit-Managers-Are-Increasing-Costs-for-Patients-and-the-Health-Care-System [https://perma.cc/T8GR-Y9Y6].

price controls to calculate a drug's MFP ceiling and inflation-linked rebates.[248]

b. Postponement of the Repeal of the Rebate Rule

The IRA additionally postpones the repeal of the "Rebate Rule," delaying potential reforms of the PBM industry.[249] The once-repealed "Rebate Rule" provides PBMs with an exception to Federal Anti-kickback laws that prohibit actors from receiving payment in exchange for Medicare business.[250] The repeal of the "Rebate Rule" sought to recognize the compensation provided to PBMs from drug manufacturers for favored formulary coverage by Part D sponsors as an illegal kickback.[251] Under the Rebate Rule's statutory safe harbor, however, PBMs are able to engage in this conduct that would otherwise be prohibited by other actors in the healthcare industry, such as doctors.[252]

In November 2020, the HHS Inspector General issued a Final Rule to remove the statutory Safe Harbor to federal Anti-kickback laws that had enabled PBM conduct,[253] citing its potential to "create a perverse incentive that rewards manufacturers for increasing their list price, while subjecting consumers to higher out-of-pocket costs."[254] The Rule would have prohibited PBMs from retaining rebates from manufacturers, instead requiring that PBMs pass on these rebates to pharmacies and Medicare Part D beneficiaries at the point of sale.[255] Before the HHS Rule went into effect, however, Section 11301 of the IRA delayed the implementation of this rule until 2032, further delaying reform of the

248. *See* CBO, PRESCRIPTION DRUGS, *supra* note 7, at 12.
249. Cubanski et al., *supra* note 16.
250. *Id.*
251. *See* Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals, 84 Fed. Reg. 2340, 2341 (proposed Feb. 6, 2019) (to be codified at 42 C.F.R. pt. 1001).
252. *See id.* at 2340.
253. 42 C.F.R. § 1001.952.
254. *Id.*; Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals, 85 Fed. Reg. 76666, 76667 (proposed Nov. 30, 2020) (to be codified as 42 C.F.R. pt. 1001.952).
255. CONG. BUDGET OFF., INCORPORATING THE EFFECTS OF THE PROPOSED RULE ON SAFE HARBORS FOR PHARMACEUTICAL REBATES IN CBO'S BUDGET PROJECTIONS—SUPPLEMENTAL MATERIAL FOR UPDATED BUDGET PROJECTIONS: 2019 TO 2029 2 (2019), https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf [hereinafter CBO, EFFECTS OF THE PROPOSED RULE ON SAFE HARBORS] [https://perma.cc/N8HN-6S77].

PBM industry.[256] While a relatively less publicized aspect of recent Medicare reform, the IRA's impact on the PBM industry and continuation of the safe harbor exception to Anti-kickback laws will have rippling consequences on the prescription drug market.[257]

PART IV: MEDICARE'S IMPACT ON PHARMACEUTICAL INNOVATION

As discussed in the previous section, limitations on Medicare's participation in the prescription drug market have inadvertently contributed to the price inflation experienced by both public and private purchasers of prescription drugs. The consequences of Medicare's purchasing decisions, however, not only impact the price of prescription drugs, but also the type of drugs that are brought to market. Here, Medicare's passivity in its prescription drug acquisitions has led to warped incentives for pharmaceutical innovation.

A. Existing Framework of Pharmaceutical Regulation

The impact of Medicare policy on pharmaceutical innovation has been obscured—in part—by the fragmented system of regulation that currently governs the U.S. pharmaceutical industry. Here, regulation is siloed by agency focus, oftentimes without coordination to broader public health objectives.[258] Three of the most prominent agencies include: (1) the U.S. Patent and Trademark Office ("USPTO"); (2) the U.S. Food and Drug Administration ("FDA"); and (3) the National Institute of Health ("NIH"), through their grant-funding program.[259] Details regarding these regulatory bodies are outlined below:

USPTO: The U.S. patent system has long played a critical role in pharmaceutical innovation through the grant of a period of market

256. Inflation Reduction Act of 2022, Pub. L. No. 117–169, § 11301, 136 Stat. 1818, 1896 (2022).

257. The total financial impact of the delay, however, has been a subject of debate. Some cost-estimates have cited the postponement of the Final Rule as a cost saving measure, supported by the fact that PBMs pass on a large share of their rebates to Medicare-sponsored plans. This estimate, however, ignores the role PBMs play in the overall inflation of retail drug prices. CBO, EFFECTS OF THE PROPOSED RULE ON SAFE HARBORS, *supra* note 255, at 2–7.

258. *See* Rachel E. Sachs, *Encouraging Interagency Collaboration: Learning From COVID-19*, 4 J. L. & INNOVATION 71, 74 (2021).

259. *See Mission and Goals, What We Do*, NAT'L INSTS. HEALTH (July 27, 2017), https://www.nih.gov/about-nih/what-we-do/mission-goals [https://perma.cc/C8VM-R67K].

exclusivity for novel drug discoveries.[260] A key determinant of the profitability of pharmaceutical companies thus hinges on determinations made by the USPTO as to whether drug discoveries qualify for patent protection. The USPTO also advises Congress and various federal agencies on intellectual property policy.[261]

FDA: The FDA regulates the safety and efficacy of drugs, biological products, and medical devices.[262] Its mission includes "advancing public health by helping to speed innovations that make medical products more effective, safer, and more affordable."[263] Before prescription drugs are sold to consumers in the U.S., they generally must undergo testing and gain FDA approval.[264]

NIH: The NIH conducts and supports research into the causes, diagnosis, prevention, and treatment of disease.[265] As the largest funder of biomedical research in the world, NIH has served as a critical driver of new pharmaceutical innovation.[266] The agency disburses over $45 billion in annual grant funding, providing research funding for nearly 300,000 researchers.[267] Many innovative new therapies are developed by small biotech companies and university-led research organizations, which often receive significant funding from NIH.[268]

In addition to the USPTO, the FDA and NIH, a variety of other governmental policy initiatives influence pharmaceutical innovation in

260. *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L. J. 544, 550 (2019) [hereinafter Hemel & Ouellette, *Innovation Policy Pluralism*]; *see also* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1616–17 (2003).

261. *See About Us*, U.S. PAT. TRADEMARK OFF., https://www.uspto.gov/about-us (last visited Mar. 19, 2024) [https://perma.cc/6VSE-64TH].

262. *See What We Do*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/what-we-do (last visited Mar. 19, 2024) [https://perma.cc/3YMS-V5PH].

263. *See id*.

264. *See* Hemel & Ouellette, *Innovation Policy Pluralism*, *supra* note 260, at 567.

265. *Budget*, NAT'L INST. HEALTH, (Oct. 24, 2023), https://www.nih.gov/about-nih/what-we-do/budget [hereinafter NIH, *Budget*] [https://perma.cc/FKL3-5U2D].

266. Robin Seaton Jefferson, *How the Largest Public Funder of Biomedical Research in the World Spends Your Money*, FORBES (Dec. 21, 2018, 1:33 PM), https://www.forbes.com/sites/robinseatonjefferson/2018/12/21/how-the-largest-public-funder-of-biomedical-research-in-the-world-spends-your-money/?sh=359fa77527b9. [https://perma.cc/7M3Y-NCUY].

267. *See* NIH, *Budget*, *supra* note 265.

268. *See* David Blumenthal, Mark E. Miller & Lovisa Gustafsson, The *U.S. Can Lower Drug Prices Without Sacrificing Innovation*, HARV. BUS. REV. (October 1, 2021), https://hbr.org/2021/10/the-u-s-can-lower-drug-prices-without-sacrificing-innovation (stating that "[i]n 2018, such small firms accounted for nearly two-thirds of the brand new drugs patented in the United States and nearly three-quarters of drugs in the late stage of the development pipeline") [https://perma.cc/7PHN-SD5Q].

particular areas. For example, the Orphan Drug Act,[269] enacted in 1983, offers tax credits and increased grant funding for the development of treatments for rare diseases.[270]

B. Medicare's Impact on Pharmaceutical R&D

While policymakers generally consider the US patent system and NIH funding decisions in isolation from Medicare spending, the impact of CMS' drug purchases may exert an equal—if not greater—impact on pharmaceutical innovation and drug development. As one of the largest (and most profitable) buyers of prescription drugs, Medicare's purchasing decision can profoundly impact pharmaceutical R&D spending.

1. DRIVERS OF INNOVATION IN THE PRESCRIPTION DRUG MARKET

Federal health insurance coverage has, until recently, been a relatively unexamined driver of pharmaceutical innovation by policymakers and academics alike.[271] Recent debates over expanding public insurance coverage, such as the formation of Medicare Part D in 2003, or the enactment of the ACA in 2010, have almost exclusively focused on the potential threats to innovation posed by government involvement in the prescription drug market, while conveniently ignoring the sizeable inflows in revenue created by the new base of customers with access to insurance coverage.[272] Here, the expansion of Medicare's prescription drug program has considerably increased the quantity of drug purchases and the related profitability of drug manufacturers.[273] As stated by Rachel Sachs, increasing seniors' access to public insurance coverage of prescription drugs "was by definition, intended to substantially increase the quantity of medications seniors were able to purchase."[274]

Although Medicare's prescription drug programs have thus far contributed to billions in increased sales to the pharmaceutical industry, a discussion of the consequences of these inflows on innovation has

269. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983).

270. Rare diseases are defined as those affecting fewer than 200,000 people in the United States. *See* Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. HEALTH ECON. 1060, 1073 (2008).

271. Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 12, at 521.

272. *See* Sachs, *The Accidental Innovation Policymakers*, *supra* note 107, at 1443.

273. *Id.*

274. *Id.* at 1452.

been terse at best.[275] Failure to address these secondary implications of government-sponsored drug spending has led to the development of, as Sachs describes, "healthcare innovation policy *by accident*,"[276] where incentives for innovation may be fundamentally misaligned with the most urgent healthcare needs.

a. Medicare as a Relatively More Profitable Market Segment

Importantly, Medicare's prescription drug program has not only flooded the market with new customers but has also made this market segment relatively more profitable for drug makers.[277] As discussed in Part III, without sufficient negotiating authority, Medicare is often made a "price-taker," or obliged to take whatever astronomical price is yielded by market averages or that result from third-party determinations.[278] Medicare's limited capacity to engage in drug price negotiations compared to most other large purchasers, such as private insurers, also increases the potential for profitability offered by the Medicare segment.

The relatively greater potential for profitability offered by the Medicare segment has created attractive financial incentives for pharmaceutical research and development. Take, for example, the potential financial success derived from developing a drug like *Humira*.[279] This blockbuster drug has been one of Medicare beneficiaries' most prescribed drugs and, until recently, has lacked generic competition.[280] Accordingly, under its mandated reimbursement formulas,[281] Medicare was forced to pay Humira's significant annual price-hikes, which bumped the price of the drug from $19,000 per year in 2012 to $38,000 per year in 2016.[282] Humira's position as not only covered by Medicare but also widely prescribed to a significant portion of the Medicare

275. *Id.* at 1460–61.
276. *Id.* at 1443.
277. *Id.* at 1444.
278. *See* discussion *supra* Part III.A.
279. Humira is used to treat arthritis, a condition prevalent in geriatric populations. *See, e.g.*, *Humira and Medicare: What to Know*, MED.NEWSTODAY (Nov. 25, 2020), https://www.medicalnewstoday.com/articles/does-medicare-cover-humira [https://perma.cc/4993-CW3X].
280. *See* Sachs, *The Accidental Innovation Policymakers*, *supra* note 107, at 1433–34.
281. *See, e.g.*, I-MAK, OVERPATENTED, OVERPRICED SPECIAL EDITION 7 (2021), https://www.i-mak.org/wp-content/uploads/2021/09/i-mak.humira.report.3.final-REVISED-2021-09-22.pdf [https://perma.cc/9JA4-PYRG].
282. Sachs, *The Accidental Innovation Policymakers*, *supra* note 107, at 1433–34.

population has helped its manufacturer, AbbVie, earn over $200 *billion* in the past twenty years.[283]

The potential financial rewards to be gained by the development of a drug like Humira can exert a powerful influence over pharmaceutical R&D strategy. These incentives have contributed to the increased flow of pharmaceutical spending towards the development of novel treatments that are likely to have a high adoption rate in the Medicare population.[284]

2. Medicare Spending's "Accidental" Impact on Innovation

Undoubtedly, the development of new treatments for any demographic offers societal benefit. The benefit conferred by a new drug discovery, however, cannot be evaluated in isolation. Rather, this benefit must also factor in the opportunity costs associated in pharmaceutical R&D decisions, where the decision to pursue one drug for development also entails a decision to forgo the development of another drug or treatment. Here, evaluation of pharmaceutical innovation must consider not only the quantity of new drugs produced but also whether such drugs meet urgent or unaddressed healthcare needs.

Because decisions to develop new drugs are made on a relative basis, a shift in R&D spending towards the larger and more profitable market for Medicare beneficiaries inevitably entails some shift away from other segments of the prescription drug market. As a result, certain diseases with low potential for favorable Medicare coverage have become relatively less attractive targets of pharmaceutical innovation.[285] In this regard, deeper analysis into the *types* of current innovation occurring in this country reveals major deficits in funding for new therapies for a variety of illnesses. Although incentives for drug innovation are derived from a variety of sources in the U.S., consideration of Medicare's "accidental" influence on drug development is necessary

283. Jonathan Gardner, *Two Decades and $200 Billion: AbbVie's Humira Monopoly Nears Its End*, BIOPHARMA DIVE (Jan. 27, 2023), https://www.biopharmadive.com/news/humira-abbvie-biosimilar-competition-monopoly/620516/ [https://perma.cc/6PJY-XT6S].

284. Research conducted by Margaret Blume-Kohout and Neeraj Sood on pharmaceutical R&D spending found that the enactment of Medicare Part D in 2003 was "associated with significant increases in preclinical testing and clinical trials for those drug classes most likely to be affected by Medicare Part D." For example, drugs with 100% of Medicare's market share corresponded with about a 27% increase in manufacturer revenue. Blume-Kohout & Sood, *supra* note 13, at 328, 335.

285. *See* Blume-Kohout & Sood, *supra* note 13, at 331.

to address the void in treatments for some of the country's most urgent needs. A number of the "unintended" incentives created by Medicare policy are outlined below:

a. Cardiovascular Disease:

Importantly, Medicare's "accidental" influence is apparent in the lack of advancement in the treatments for cardiovascular disease, the leading cause of death in the United States. Here, Medicare's comparatively less favorable pricing approach for cardiovascular disease treatments has corresponded with a sharp decline in new drug development in this area, notwithstanding the continued high disease incidence.[286] As stated by Hemel and Oullette, the relatively lower potential for profitability derived from cardiovascular treatments under Medicare's reimbursement scheme has "[i]n effect . . . deprioritized drugs that target the number one killer in the country."[287] Furthermore, the significantly higher fatality rates for cardiovascular disease in African American populations,[288] reveals how warped innovation incentives can lead to particularly dire consequences for certain populations.[289]

b. Prevention:

Additionally, Medicare's influence on pharmaceutical R&D spending has contributed to the broad shift in development away from *prevention* and towards *treatments,* especially of long-term, chronic conditions. This trend is apparent in the boom in "blockbuster" drugs, which often treat conditions prevalent in the geriatric population, and the concurrent decline in development of vaccines, which provide substantial societal benefit across age demographics to prevent illness in the first place.[290]

286. Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 12, at 524 (noting that "[t]he Medicare Act gives pharmaceutical firms less pricing power with respect to cardiovascular drugs than to other common drug classes").

287. *Id.*

288. *See, e.g.*, Mercedes R. Carnethon, Jia Pu, George Howard, Michelle A. Albert, Cheryl A. M. Anderson, Alain G. Bertoni, Mahasin S. Mujahid, Latha Palaniappan, Herman A. Taylor Jr., Monte Willis & Clyde W. Yancy, *Cardiovascular Health in African Americans: A Scientific Statement from the American Heart Association*, 136 CIRCULATION 393, 394 (2017).

289. *See* Sachs, *The Accidental Innovation Policymakers*, *supra* note 107, at 1439.

290. Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 12, at 528–34.

c. Medicaid Coverage:

Discrepancies in the reimbursement methodology used by Medicare and other government drug programs have also had an effect on pharmaceutical innovation. In particular, Medicaid, a public insurance program run jointly by federal and state governments for those below a certain income threshold, pays on average significantly less for its prescription drugs than Medicare.[291] Findings from a 2021 Congressional Budget Office study reveal that the net average price of a basket of top selling brand-name drugs cost Medicaid a third of what it costs Medicare, largely due to differences in the two programs' reimbursement schemes and rebate obligations.[292] These discrepancies were even greater in the case of specialty drugs, which cost on average $1,889 when covered by Medicaid but $4,293 when covered by Medicare Part D.[293] The relatively low potential for profitability offered by Medicaid's drug program makes treatments for diseases with high incidence in the Medicaid population relatively less attractive therapeutic targets for drug manufacturers.[294] The generally less-favorable reimbursement scheme under Medicaid, predictably, creates incentives for pharmaceutical companies to prioritize research and development efforts on drugs addressing the health concerns of the Medicare, rather than the Medicaid, population.[295]

d. Children and Young Adults:

Similarly, children and young adults are disproportionately disadvantaged in Medicare's "accidental" drug development incentive structure, exacerbating the existing financial disincentives surrounding

291. *See* CBO, COMPARISON OF BRAND-NAME DRUG PRICES, *supra* note 7, at 2.

292. More specifically, 176 of the top-selling brand name drugs had an average sales price of $118 under Medicaid's reimbursement scheme, but $343 under Medicare Part D. *See id.* at 15.

293. *Id.* at 2.

294. *See Medicaid-to-Medicare Fee Index 2019*, KKF, https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index/ (last visited Mar. 19, 2024) [https://perma.cc/F7KZ-U4HU].

295. *See* Laura M. Keohane & Ann Hwang, *Payment Policy and The Challenges of Medicare and Medicaid Integration for Dual-Eligible Beneficiaries*, HEALTH AFFS. (Oct. 20, 2022), https://www.healthaffairs.org/do/10.1377/hpb20220923.93608/ [https://perma.cc/5HP9-ZCJ4].

the treatment of childhood illness.[296] Due to age-based eligibility requirements, children are generally excluded from enrollment in Medicare.[297] Instead, the largest insurer of children in the U.S. is Medicaid, which, as discussed above, often offers comparatively less profitable drug reimbursement rates compared to Medicare.[298] These financial disincentives are further compounded by the comparatively lower reimbursement rates that Medicaid provides to doctors for office visits, which are on average seventy-two percent of Medicare's reimbursement rates.[299] Here, Medicaid's lower reimbursement to doctors has been correlated with decreases in the number of Medicaid-covered children that receive care from physicians for basic healthcare needs.[300] Without access to prescribers, such as primary care doctors, children are also much less likely to be taking prescription drugs and treatments—further lowering the number of potential customers in the pediatric market, especially when compared to the elderly population.[301] As stated by Shetal Shah and Heather Brumberg in *Improving Access by Reducing Medicaid-to-Medicare Payment Disparities*, Medicaid's lower payment scale "represents a historical de-valuation of children and a misunderstanding of the importance of care provided by pediatricians."[302]

As a result, in decisions on how to spend limited resources on R&D, Big Pharma may be inclined to overlook the pediatric market, which is not only smaller in size but also heavily reliant on Medicaid's less profitable reimbursement rates.[303] Instead, pharmaceuticals are

296. *See* Esther M. Speer, Lois K. Lee, Florence T. Bourgeois, Daniel Gitterman, William W. Hay Jr., Jonathan M. Davis & Joyce R. Javier, *The State and Future of Pediatric Research—an Introductory Overview*, PEDIATRIC RSCH. (2023), https://www.nature.com/articles/s41390-022-02439-4 [https://perma.cc/478V-Q3WN]. The deficit in pediatric innovation is also influenced by heightened regulatory and safety standards, among other factors.

297. As discussed previously, Medicare is generally only available for those who are older than 65 or those with certain disabilities. *See supra* text accompanying note 76.

298. *See* Shetal Shah, Alice A. Kuo & Heather L. Brumberg, *First Aid for Medicaid: Losses in Children's Health Insurance*, 89 PEDIATRIC RSCH. 8, 8 (2021), https://www.nature.com/articles/s41390-020-01219-2 [https://perma.cc/B8N6-CWSX].

299. Shetal Shah & Heather L. Brumberg, *Improving Access by Reducing Medicaid-to-Medicare Payment Disparities: Congenital Heart Disease and Beyond*, 91 PEDIATRIC RSCH. 1636, 1638 (Mar. 2022), https://www.nature.com/articles/s41390-022-02039-2 [https://perma.cc/4XTN-LBW8].

300. *See* Shah et al., *supra* note 298, at 9.

301. *See id.*

302. Shah & Brumberg, *supra* note 299, at 1636.

303. *See id.*

likely to favor the development of drugs with a more certain return on investment, such as those expected to be adopted by the larger and more profitable Medicare population.[304]

Such disincentives contribute to the dearth in pediatric drug and device development and the tragic pediatric outcomes in the U.S., such as the lowest life expectancy at birth and the highest infant and maternal mortality rates.[305] By contrast, treatments likely to be covered by Medicare have blossomed.[306] For example, new drug development for the treatment of cancer, which is common in older adults,[307] and nervous system disorders, such as Alzheimer's and Parkinson's disease, have experienced twice the growth as the three next largest classes of treatments combined.[308]

3. THE IMPACT OF THE IRA ON PHARMACEUTICAL INNOVATION

As mentioned earlier, the IRA's cost-controlling provisions contain a robust list of exceptions.[309] Here, the IRA's limited applicability is likely to influence a shift in R&D efforts towards the broad range of treatments that are excluded from eligibility for the IRAs price controls.[310] Drugs currently ineligible for IRA price controls, such as biologics, which frequently require injections or intravenous

304. *See also* Efraim Benmelech, Janice C. Eberly, Joshua L. Krieger & Dimitris Papanikolaou, *Private and Social Returns to R&D: Drug Development and Demographics*, NAT'L BUREAU ECON. RSCH. (Jan. 2021), http://www.nber.org/papers/w28355 [https://perma.cc/A5UJ-8NU7] (revealing the increased share of research and development spending being channeled to the geriatric populations, with over half of all new preclinical drug development targeting treatments for aging adults). *See generally* Keohane & Hwang, *supra* note 295.

305. Based on results of a 2021 study by the RAND Corporation, which compared drug prices in the United States with thirty-two other countries. *See* Thomas Waldrop, *Value-Based Pricing of Prescription Drugs Benefits Patients and Promotes Innovation*, CTR. FOR AM. PROGRESS (Sept. 13, 2021), https://www.americanprogress.org/article/value-based-pricing-prescription-drugs-benefits-patients-promotes-innovation/ [https://perma.cc/99RW-6H8P].

306. *See generally* CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (2021), https://www.cbo.gov/publication/57126 [hereinafter CBO, R&D IN THE PHARM. INDUS.] [https://perma.cc/8AWE-HXQG].

307. Cancer predominately afflicts older adults; nine out of ten cancer diagnoses in the U.S. in recent years were in people 45 and older. Kendall K. Morgan, *Cancer Incidence Rates by Age*, WEBMD (Nov. 7, 2022), https://www.webmd.com/cancer/cancer-incidence-age [https://perma.cc/24SA-7FSC].

308. CBO, R&D IN THE PHARM. INDUS., *supra* note 306, at 9.

309. *See supra* Part II.

310. *See* Sullivan, *supra* note 155, at 394–99.

administration, or Orphan drugs,[311] which treat "rare diseases," i.e., those that affect fewer than 200,000 people in the United States, are likely to experience an increase in research and development spending.[312] While innovation in excluded-classes of drugs, such as biologics, is likely to yield valuable advances in these types of therapies, the IRA's exclusionary criteria does not appear to be reflective of a deliberate effort to spur drug development in areas where it is most urgently needed.

a. Small Molecule Drugs

Small molecule drugs, which are typically used in oral therapies such as blood pressure medications, cholesterol drugs, and common medications, like aspirin, are not subject to one of the IRA's exceptions to drug pricing controls.[313] The comparative eligibility of small molecule drugs for MFP negotiations is likely to discourage new investment spending for these medications, notwithstanding their importance in treating disease.[314] As stated by the CEO of one large drug manufacturer, Eli Lilly, "[i]n 10 years, we'll have far fewer small molecules being developed than we do today."[315] Concern over drug eligibility for IRA price controls has already been cited as the reason Eli Lilly decided to

311. *See* Sarah Jane Tribble & Sydney Lupkin, *High Prices for Orphan Drugs Strain Families and Insurers*, NPR (Jan. 17, 2017, 1:36 PM), https://www.npr.org/sections/health-shots/2017/01/17/509507035/high-prices-for-orphan-drugs-strain-families-and-insurers [https://perma.cc/S6GL-JNJB].

312. *See id.*

313. Deena Beasley, *Focus: Drug Companies Favor Biotech Meds over Pills, Citing New U.S. Law*, REUTERS (Jan. 13, 2023, 8:53 AM), https://www.reuters.com/business/healthcare-pharmaceuticals/drug-companies-favor-biotech-meds-over-pills-citing-new-us-law-2023-01-13/ [https://perma.cc/H5JY-SC9F].

314. *See, e.g.*, Linda Kesselring, *The Differences Between Small Molecule Drugs and Biological Drugs?*, EMORY TECH. TRANSFER BLOG (Feb. 16, 2021), https://web.archive.org/web/20230926084901/https://scholarblogs.emory.edu/techtransfer/2021/02/the-differences-between-small-molecule-drugs-and-biological-drugs/ [https://perma.cc/68J6-2T6J] (stating "[s]mall molecule drugs, as their name suggests, are chemical compounds that have low molecular weight—a single molecule of a small molecular drug typically contains only 20 to 100 atoms. They can enter cells easily where they interact with molecules within the cell.").

315. Richard G. Frank & Ro W. Huang, *Early Claims and M&A Activity Following Enactment of the Drug Provisions of the IRA*, BROOKINGS INST. (Aug. 23, 2023), https://www.brookings.edu/articles/early-claims-and-ma-behavior-following-enactment-of-the-drug-provisions-in-the-ira/ [https://perma.cc/5295-48GK].

terminate investment in an ongoing leukemia research project.[316] Additionally, another drug manufacturer, Alnylam Pharmaceuticals, announced that it was suspending development of a treatment for an eye disease, presumably out of concern that the drug would be subject to IRA price negotiation provisions.[317]

b. Evading of IRA Eligibility

On the flipside, the IRA's disfavored treatment of orally available drugs is likely to shift innovation towards non-IRA-eligible biologics, which are administered intravenously or through injection. Dissuading orally available treatment options, however, runs contrary to many patients' preferences.[318] Furthermore, this shift is likely to increase overall Medicare spending since orally available drugs tend to be less costly to administer.[319]

Similarly questionable, the exclusion of "Orphan Drugs" from the IRA encourages drug development for diseases that—by definition—are least common in the population.[320] While the Orphan Drug designation has been an important public health initiative to incentivize the development of treatments that may otherwise be unprofitable because of their small segment size, Medicare's additional exclusion of Orphan Drugs under the IRA may "overshoot" this public health objective. Here, the additional financial incentives created by the IRA to develop Orphan Drugs may promote an excessive shift in spending *away* from the development of treatments for disorders that affect larger segments of the population. Furthermore, without additional price-controls, new

316. Joe Grogan, *The Inflation Reduction Act is Already Killing Potential Cures*, WALL ST. J. (Nov. 3, 2022, 6:20 PM), https://www.wsj.com/articles/the-inflation-reduction-act-killing-potential-cures-pharmaceutical-companies-treatment-patients-drugs-prescriptions-ira-manufacturers-11667508291 [https://perma.cc/3RDY-WL3J].

317. *See id*.

318. Mohammed S. Alqahtani, Mohsin Kazi, Mohammad A. Alsenaidy & Muhammed Z. Ahmad, *Advances in Oral Drug Delivery*, 12 FRONTIERS IN PHARMACOLOGY, 2021, at 1, https://www.frontiersin.org/articles/10.3389/fphar.2021.618411/full [https://perma.cc/3JCC-8NX4] (stating that orally administered medications are the "most preferred route, due to its advantages, such as non-invasiveness, patient compliance and convenience of drug administration").

319. *See id*.

320. The Orphan Drug designation was created under the Orphan Drug Act to encourage the development of treatments for rare diseases by offering certain funding, cost-reimbursement, and more favorable treatment in the approval process. *See* Orphan Drug Act, Pub. L. No. 97–414 96 Stat. 2049 (2013).

Orphan Drug development does not necessarily mean those with rare diseases will have access to additional treatment options. Even before the passage of the IRA, the rising prices of many Orphan Drug treatments, which often cost over $100,000 per year, have led to concerns that while there may be increased innovation in the treatment of Orphan diseases, individual access to these novel therapies will remain restricted due to their high prices.[321]

PART V: ESTABLISHMENT OF CENTRALIZED OVERSIGHT

A. Central Oversight of Prescription Drug Policy

As thus far discussed, limitations in Medicare's prescription drug program not only undermine Medicare's long-term financial sustainability but also contribute to a host of unintended pricing distortions and "accidental" incentives for innovation.[322] To remedy these ills, Medicare should abandon its position as a passive participant in the prescription drug market and instead adopt an active role in fair pricing determinations. Due to its influence on broader market pricing and incentives for innovation, Medicare's assessment of a drug's fair value should not only reflect its own policy objectives, but also consider the secondary consequences of its purchasing decisions on other purchasers in the marketplace.

To achieve these objectives, this Article proposes replacing the existing system of disjointed healthcare regulatory oversight with a central, independent body charged with overseeing federal healthcare spending. This proposed agency should be composed of experts to assess the country's current healthcare needs and whether they are addressed by existing policy choices. The agency's development of long-term healthcare objectives would then be used to inform coordinated oversight of the pharmaceutical industry. Regulatory functions would include: (1) standardizing fair price determinations for prescription drugs covered by public insurance programs; and (2) aligning inter-

321. *See* CAROLINE PEARSON, LINDSEY SCHAPIRO & STEVEN D. PEARSON, INST. FOR CLINICAL & ECON. REV., THE NEXT GENERATION OF RARE DISEASE DRUG POLICY: ENSURING BOTH INNOVATION AND AFFORDABILITY 8 (2022), https://icer.org/wp-content/uploads/2022/04/ICER-White-Paper_The-Next-Generation-of-Rare-Disease-Drug-Policy_040722.pdf [https://perma.cc/GQT6-97W7].

322. *See supra* Parts II & IV.

agency incentives for pharmaceutical innovation with broader healthcare policy objectives.

1. VALUE-BASED PRICING MODELS

In order to implement the type of value-based pricing that has proved effective in other countries, the United States needs to devise a paradigm for assessing the relative "value" of a particular drug. An independent third-party commission whose members include leading scientists and researchers should be charged with assessing a drug's clinical benefit, not only during clinical trials before drug approval, but also periodically throughout the drug's distribution life.

a. Existing Models for Design

The structure and operations of this commission could be modeled after the Institute for Clinical and Economic Review ("ICER"), a private company founded through Harvard Medical School in 2006.[323] ICER currently performs reviews of numerous drugs, and its assessments are sometimes used by insurance companies when negotiating prices.[324] ICER was founded because "[t]he US health system is distinctly innovative but fails to provide high-value care to all patients at a price they and the nation can afford," and its stated objective is "[t]o improve access and affordability while retaining the incentives necessary for future innovation."[325] It uses a process which "transparently reviews all available evidence to help align a treatment's price with how well it improves the lives of patients and their families."[326] Notably, although ICER studies drug pricing in foreign countries, it has also created "a robust evidence rating matrix" that is "uniquely suited for the uniquely American health care system."[327]

The U.S. has already devoted significant funding to compare medical treatments to determine the best course of treatment for

323. *See History & Impact*, ICER, https://icer.org/who-we-are/history-impact/ (last visited Mar. 19, 2024) [hereinafter ICER, *History & Impact*] [https://perma.cc/T294-X7Z6].

324. *Id*.

325. *Who We Are*, ICER, https://icer.org/who-we-are/ (last visited Mar. 19, 2024) [https://perma.cc/K8DP-2NR5].

326. *Id.*

327. ICER, *History & Impact*, *supra* note 323.

patients.[328] In 2009, under the American Recovery and Reinvestment Act ("ARRA"),[329] Congress appropriated $1.1 billion in federal funding to pursue CER research and directed the Institute of Medicine ("IOM") to recommend national public health strategies.[330] This act called for coordination of comparative effectiveness research across the federal government.[331] Additionally, the proposed federal agency could build upon existing efforts, such as the NIH's Advanced Research Projects Authority for Health ("ARPA-H"), which seeks to develop breakthrough research discoveries into viable treatments and healthcare solutions,[332] and unify the existing system of fragmented regulation.

b. Incorporation of Value-Based Criteria

Furthermore, the ACA, as noted previously, established and funded the PCORI, a nonprofit corporation whose primary objective "is to assist patients, clinicians, purchasers, and policy makers in making informed health decisions."[333] Presently, however, Medicare is unable to make effective use of PCORI data. As discussed above, section 1182(e) of the ACA prohibits the use of "adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs" under Medicare.[334] While metrics such as QALY may be imperfect, there is a dire need for measures which quantify, as objectively as possible, how much value a particular treatment provides in terms of improving and extending human life. Accordingly, legislative prohibitions on the use of comparative effectiveness research in making medical pricing determinations should be repealed.

328. *See* American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115, 117.

329. *Id.*

330. *Id*.

331. *Id.*

332. ARPA-H is a new federal agency established which was established in 2022. *See HHS Secretary Becerra Establishes ARPA-H within NIH, Names Adam H. Russell, D.Phil. Acting Deputy Director*, U.S. DEPT. HEALTH & HUM. SERV. (May 25, 2022), https://www.hhs.gov/about/news/2022/05/25/hhs-secretary-becerra-establishes-arpa-h-within-nih-names-adam-h-russell-phil-acting-deputy-director.html [https://perma.cc/64VF-8LK2].

333. Kumar Mukherjee, *Pharamcoeconomics and Outcomes*, PCOM (Jan. 25, 2023), https://www.pcom.edu/academics/programs-and-degrees/doctor-of-pharmacy/school-of-pharmacy/blog/pharmacoeconomics-and-outcomes-research.html/ [https://perma.cc/7QJM-HYEW].

334. 42 U.S.C. 1320e-1(e).

2. COORDINATED PRESCRIPTION DRUG POLICY

a. Congruent Reimbursement Schemes

This country's fragmented healthcare system, with its wide array of participants and various regulators, reduces incentives to consider the broader implications of health dollar allocation decisions. The proposed centralized agency would firstly standardize pricing determinations across government-sponsored health insurance programs, for, as Shah and Brumberg state, "movement toward Medicaid parity with Medicare has been piecemeal and unacceptably slow."[335] Uniform reimbursement rates across federal programs, such as Medicare, Medicaid, and the VA, would help address innovation disparities that exist between programs due to differences in pricing methodology and rebate calculations, which, as noted previously, can make certain demographics comparatively less profitable due to lower per-patient revenue.[336]

3. ESTABLISHMENT OF FAIR PRICING METHODOLOGY

Using its expertise and central oversight, the proposed agency should develop criteria to engage in fair drug price evaluations, akin to assessments made by agencies in other countries, such as in Germany's multi-payer system.[337] The criteria used by the agency to value a prescription drug should be chosen deliberately and avoid current Medicare pitfalls by relying too heavily on average market prices. Eliminating the rigid, formulaic adoption of market-based metrics will reduce drug makers' incentives to raise prices paid by other market participants.

Although the proposed agency will likely lack the authority to influence private market prices, the mere establishment of fair pricing criteria for government-sponsored drug purchases can inform other insurers and consumers of reasonable standards for prescription drug costs. Establishing value-based prices that apply broadly across populations with varying insurance coverage will help to eliminate the problem of cost-shifting, where, for example, a drugmaker attempts to recoup lost revenue for a particular drug in the Medicare marketplace by increasing prices for that drug in the private insurance market. The

335. Shah & Brumberg, *supra* note 299, at 1637.
336. *See* Sachs, *Delinking*, *supra* note 224, at 2351–56.
337. *See supra* Part I.B.1.a.

adoption of broadly applicable standards for drug prices is especially important for those lacking insurance coverage. Despite the initial promise of the ACA, it is expected that the number of uninsured people is expected to rise to 37.2 million by 2028.[338]

a. Creating Intentional Incentives for Drug Innovation

By taking an active role in price determinations, the government can better control the inevitable influence it exerts through its mammoth buying power. Strategic spending decisions can channel this influence to incentivize the development of solutions to address the countries' most urgent healthcare needs. In addition to controlling excessive costs, the agency's fair pricing determinations could make intentional the "accidental" incentives for innovation created by government prescription drug purchases.[339] Here, the agency should base its pricing criteria on an independent assessment of the country's most urgent medical needs and long-term healthcare policy objectives. By aligning pricing criteria with a drug's added value, the agency can deliberately channel dollars for pharmaceutical innovation to addressing public health priorities and the treatment of medical conditions that currently lack effective treatments.

Use of qualitative criteria could reverse the current undervaluing of drug development in critical areas, such as infant and early childhood mortality. For example, using criteria such as additional years of life provided by a drug to calculate its fair price would bolster the value of treatments that prevent infant mortality (since such treatments presumably have the greatest potential to add years of life). Additionally, implementation of pricing determinations by a centralized agency would prevent various government programs from narrowly pursuing their own short-term priorities at the expense of the country's long-term healthcare objectives. For example, Medicare policy priorities currently are, as a general matter, limited to the interests of the elderly.

A centralized agency could also better balance healthcare considerations across time and between demographics in its pricing determinations. Here, value-based factors could include a drug's long-term

338. *See* Sean P. Keehan, Gigi A. Cuckler, John A. Poisal, Andrea M. Sisko, Sheila D. Smith, Andrew J. Madison, Kathryn E. Rennie, Jacqueline A. Fiore & James C. Hardesty, *National Health Expenditure Projections, 2019–28: Expected Rebound in Prices Drives Rising Spending Growth*, 39 HEALTH AFFS. 704, 706 (2020).

339. *See* Sachs, *Delinking*, *supra* note 224, at 1431.

cost savings across government spending programs. Rewarding these long-term public health benefits would bolster the lackluster incentives currently available to develop preventative treatments, such as childhood vaccines.

b. Coordinated Policy Objectives

In addition to aligning the incentives for innovation created by government-sponsored prescription drug purchases, this centralized body should coordinate its policy objectives with other government entities influencing pharmaceutical behavior, such as the FDA and the USPTO.[340] Coordinated action by regulators would ensure that federal interventions do not create conflicting incentives. A centralized body could balance the sometimes-competing interests pursued by different agencies. Importantly, this centralized agency could apply ongoing comparative effectiveness research conducted by PCORI to consider long-term healthcare priorities "where appropriate investment and coordination will enable immediate progress."[341]

Developing new prescription drugs can be extremely time-consuming and expensive.[342] Despite their high development costs, however, such drugs can have an enormously valuable impact, both extending and improving human lives.[343] It is critically important, therefore, that any value-based drug pricing scheme retains sufficient financial incentives to promote drug discovery and development. A centralized healthcare agency could coordinate with the FDA and the USPTO to ensure that drug pricing regimes, FDA approval metrics, and grants of patent exclusivity adequately incentivize the most urgently needed pharmaceutical innovation.

This coordinated policymaking could be particularly useful in informing Medicare's coverage determinations. Here, collaboration with other drug regulators on drug efficacy and relative clinical benefit

340. *See generally* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012).

341. Olsen et al., *supra* note 41, at 58–59.

342. *See, e.g.*, STEPHEN EZELL, INFO. TECH. & INNOVATION FOUND. ENSURING U.S. BIOPHARMACEUTICAL COMPETITIVENESS 29 (2020), https://www2.itif.org/2020-biopharma-competitiveness.pdf [https://perma.cc/S3PD-J5QA].

343. *See, e.g.*, Robin Feldman, *The Perils of Value-Based Pricing for Prescription Drugs*, WASH. POST (Apr. 11, 2019, 6:00 AM), https://www.washingtonpost.com/outlook/2019/04/11/perils-value-based-pricing-prescription-drugs [https://perma.cc/JJ8B-76CE].

could circumvent the need to rely on intermediaries such as private insurers and PBMs to make drug coverage decisions.

4. COMBATTING LEGAL CHALLENGES

Inter-agency coordination could also utilize regulators' existing grants of legal authority to promote needed changes. As Alfred B. Engelberg discusses in *A New Way to Contain Unaffordable Medication Costs, Exercising the Government's Existing Rights*, existing patent laws, such as The Bayh–Dole Act of 1980,[344] already provide a sound legal basis for regulatory intervention into government-funded pharmaceutical development.[345] Here, the creation of a regulatory body with clear authority to engage in value-based assessments for drugs would solve many of the seemingly intractable problems created by the negotiation and rebate provisions of the IRA.

First, the creation of an independent body to establish fair drug prices would eliminate the fiction that the IRA grants Medicare overly-broad authority to unilaterally set prices for certain drugs. Second, the new regulatory body would have a more extensive reach than that provided by the IRA which, as noted, extends to only a limited subset of drugs. Finally, unlike in the IRA-designed scheme, where the process for setting drug prices remains opaque and subject to manipulation by the myriad participants in the drug delivery ecosystem, the new prescription drug regulatory body could establish a transparent process for evaluating drug efficacy and pricing data and for allocating research and development dollars to those segments of the healthcare marketplace with the most compelling needs.

B. Potential Hurdles to Implementation

Implementing such reform will likely pose a myriad of practical and legal challenges. As the first step, Congress would need to repeal existing statutory constraints, such as section 1182(e) of the ACA, which generally prohibits Medicare from using cost-effectiveness analyses.[346] Additionally, such reform would entail surmounting opposition from

344. A provision in the Bayh–Dole Act of 1980, 35 U.S.C. § 200-212, while never before exercised, grants the government the right to use patented technology that was created using federal funding. Alfred B. Engelberg, Jerry Avorn & Aaron S. Kesselheim, *A New Way to Contain Unaffordable Medication Costs—Exercising the Government's Existing Rights*, 386 NEW. ENG. J. MED. 1104, 1104 (2022).

345. *Id.* at 1104–05.

346. 42 U.S.C. 1320e-1.

certain politically potent groups. In particular, the pharmaceutical industry is likely to loudly object to national value-based drug pricing, arguing that it will hinder innovation and slow the development of new life-saving therapies. Here, there is a pervasive perception that drug pricing reform and encouraging pharmaceutical innovation are mutually exclusive.[347] A deeper analysis of the factors driving pharmaceutical innovation, however, reveals a less persuasive claim.

Undoubtedly, drug manufacturers should be adequately compensated to provide the resources needed to finance future pharmaceutical innovation, as "[d]eveloping a new medicine is a long and complex process, with risk of failure at each step."[348] Indeed, the average cost of developing a new drug and obtaining FDA approval is $2.6 billion and the process takes on average ten to fifteen years to finish.[349] As described by Rena M. Conti, Richard Frank & Jonathan Gruber in *Addressing the Trade-Off Between Lower Drug Prices and Incentives for Pharmaceutical Innovation,* the "fundamental dilemma" of prescription drug pricing reform is its threat to continued pharmaceutical innovation.[350]

On the opposing side, critics, such as Avik Roy in *The Competition Prescription: A Market-Based Plan for Affordable Drugs*, assert that "with a modicum of scrutiny" the flaws in the argument that increased drug spending is necessary to spur innovation become apparent.[351] In Roy's

347. As Rena Conti states, "the dilemma facing policymakers is perceived to be that controlling drug prices now necessarily means fewer new drugs tomorrow." Rena Conti, Richard G. Frank & Jonathan Gruber, *Addressing the Trade-Off Between Lower Drug Prices and Incentives for Pharmaceutical Innovation*, BROOKINGS (Nov. 15, 2021), https://www.brookings.edu/essay/addressing-the-trade-off-between-lower-drug-prices-and-incentives-for-pharmaceutical-innovation/ [https://perma.cc/QM42-8AU6].

348. PHRMA, INNOVATION IN THE BIOPHARMACEUTICAL PIPELINE 6 (2021), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Innovation_in_Biopharmaceuticals.pdf [https://perma.cc/9253-U8GK] (stating that "[w]hile hundreds of thousands, or even millions, of compounds may be screened as part of large-scale libraries, and thousands of new medicine candidates are further screened in the laboratory, only one may eventually result in an FDA-approved medicine, after many years of testing").

349. TUFTS CTR. FOR STUDY DRUG DEV., COST TO DEVELOP AND WIN MARKETING APPROVAL FOR A NEW DRUG IS $2.6 BILLION, TUFTS CTR. FOR THE STUDY OF DRUG DEV 1 (2014), https://f.hubspotusercontent10.net/hubfs/9468915/TuftsCSDD_June2021/pdf/pr-coststudy.pdf [https://perma.cc/UG8N-5853].

350. Conti et al., *supra* note 347.

351. Avik Roy, *The Competition Prescription: A Market-Based Plan for Affordable Drugs*, MEDIUM: FREOPP (May 16, 2017), https://freopp.org/a-market-based-plan-for-affordable-prescription-drugs-931e31024e08 (stating "put simply, drug companies charge the highest prices where they have the greatest market power: generally,

view, drug prices are based on market exclusivity, rather than their cost of production.[352] Looking at U.S. healthcare outcomes further calls into question any direct link between drug spending and innovation. As discussed previously, while persons living in the U.S. pay twice or even three times as much as those living in other countries for their prescription drugs, this country has the lowest life expectancy at birth, the highest rate of population with multiple chronic conditions,[353] and the highest infant and maternal mortality rates of all high-income countries.[354] These dismal U.S. health outcomes undermine the assumption that higher drug prices fuel pharmaceutical innovation.

As one commentator notes, "amidst predictions that legislative price ceilings will hinder pharmaceutical innovation, competing data suggest this fear is overstated."[355] Indeed, one study which compared drug innovation in the U.S. with that in other developed countries concluded that "[h]igher prescription drug spending in the United States does not disproportionately privilege domestic innovation." [356] As indicated by this study, many countries with more stringent pricing controls still maintained strong levels of pharmaceutical research and innovation.[357]

CONCLUSION

Medicare's prescription drug program, while covering only a portion of Americans, has an outsized influence on the broader population's access to medicine. Flaws in Medicare design have contributed not only to astronomical drug costs but also to growing voids in innovation targeting the most urgent public health priorities. While the recently enacted IRA seeks to provide Medicare with greater authority to

because they have developed a drug for a disease for which they have no competition") [https://perma.cc/K2C5-PYQ2].

352. *Id*.

353. Chronic conditions include diseases such as asthma, cancer, depression, diabetes, heart disease, and hypertension. *See* Munira Z. Gunja, Evan D. Gumas & Reginald D. Williams II, *U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes*, COMMONWEALTH FUND (Jan. 31, 2023), https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022 [https://perma.cc/AF2V-P8JD].

354. *Id.*

355. Willard, *supra* note 91, at 599.

356. *See* Salomeh Keyhani, Steven Wang, Paul Hebert, Daniel Carpenter & Gerard Anderson, *US Pharmaceutical Innovation in an International Context*, 100 AM. J. PUB. HEALTH 1075, 1079 (2010).

357. *Id*.

lower drug prices, its narrow applicability and continued reliance on industry participants for pricing determinations will likely limit its ability to bring about meaningful cost controls. The IRA's shortcomings highlight the need for comprehensive industry reform. Rather than attempting small fixes to the current Medicare prescription drug paradigm, a coordinated system of pharmaceutical oversight should inform Medicare policy to better align the direct and indirect consequences of Medicare's drug purchases with broader public health objectives. Such an approach would reduce drug costs, not only for those who are Medicare-eligible but also for the general population and would provide incentives to develop drugs to effectively treat patients who currently lack effective therapies.

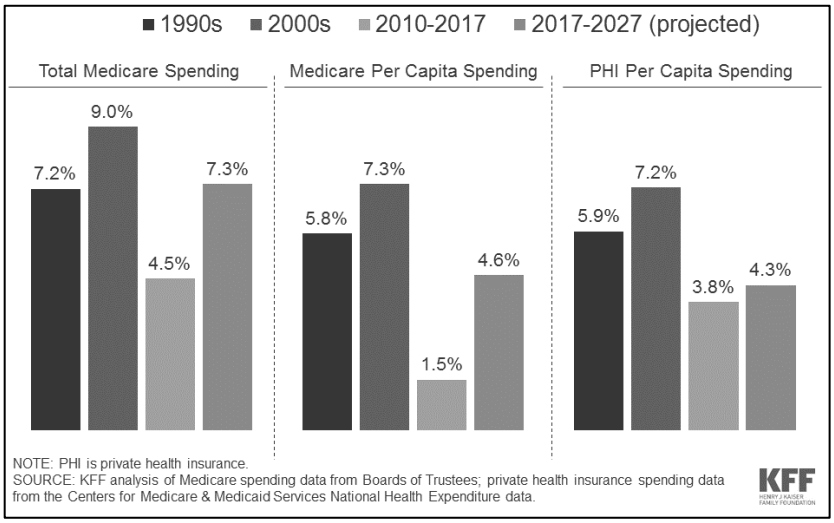
APPENDIX

FIGURE 1. COMPARISON OF SELECTED FEDERAL PROGRAMS PROVIDING OUTPATIENT PRESCRIPTION DRUG COVERAGE[358]

	Medicare Part D	Medicaid	VA Prime Vendor Program	DoD TRICARE Program
Eligibility	People age 65 or older who paid Medicare payroll taxes for at least 10 years; certain younger people who have received Social Security disability benefits for at least two years or who have end-stage renal disease or amyotrophic lateral sclerosis.	States are required to cover certain low-income individuals, including children and their parents, pregnant women, people with disabilities, and people age 65 or older. States may choose to cover other groups, such as low-income adults without dependent children and people receiving home- and community-based services.	Veterans who have served on active duty (including reservists) and who did not receive a dishonorable discharge may be eligible for VA health care benefits. While most such veterans qualify, their length of service, income, and service-connected disabilities may affect their access to VA health care.	Active-duty and retired military and dependents.
Where Prescriptions Are Filled	Private pharmacies, including mail-order pharmacies.	Participating private pharmacies, including mail-order pharmacies.	VA medical facilities or VA mail-order pharmacy.[a]	Military treatment facilities; TRICARE mail-order pharmacy; TRICARE retail network pharmacies; nonnetwork pharmacies.
Covered Drugs	Plan sponsors develop their own list of covered drugs subject to certain requirements. Plans may steer enrollees toward preferred drugs by requiring higher copayments or requiring prior authorization for nonpreferred drugs.	States must cover all drugs made by manufacturers that have entered into a rebate agreement with CMS, except for drugs used for a limited set of conditions specified by federal law. Each state may develop a list of preferred drugs and require prior authorization or higher copayments for drugs not on that list.	VA develops a national formulary with a list of preferred dugs and steers patients toward those drugs by requiring prior authorization and, in some cases, higher copayments for drugs not on that list.	DoD develops a national formulary with a list of preferred dugs and steers patients toward those drugs by requiring prior authorization and, in some cases, higher copayments for drugs not on that list.
How Prices Are Determined	Negotiations between Part D plans (or their PBMs) and manufacturers. Plans might receive price concessions in exchange for including preferred drugs in their formularies. Manufacturers are also required to give discounts on brand-name drugs when enrollees are within a specified range of spending on covered drugs.	In fee-for-service systems, state Medicaid agencies set payments to pharmacies; in managed care arrangements, plans typically contract with a PBM to negotiate payment rates with pharmacies. In both cases, net prices are heavily influenced by rebates that drug manufacturers must pay to Medicaid.	Price available to the Big Four (minimum of federal supply schedule price and federal ceiling price) is a starting point for further potential price concessions based on inclusion in preferred drug formularies.[b]	Price available to the Big Four (minimum of federal supply schedule price and federal ceiling price) is a starting point for further potential price concessions based on inclusion in preferred drug formularies.[b]
Total Federal Expenditures in 2018 (Billions of dollars)[c]	**88.3[d]**	**21.8[e]**	**7.2[f]**	**7.7[g]**

358. See CBO, COMPARISON OF BRAND-NAME DRUG PRICES, *supra* note 74, at 4–5.

FIGURE 2. ACTUAL AND PROJECTED AVERAGE ANNUAL GROWTH RATES IN MEDICARE AND PRIVATE HEALTH INSURANCE SPENDING, 1990–2027[359]



359. *Overview of Medicare*, KFF (Feb. 13, 2019), https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/ [https://perma.cc/5YKE-MG6F].