Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Responses and Potential Effects

December 8, 2023

Congressional Research Service
https://crsreports.congress.gov
R47872

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SUMMARY

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Kevin J. Hickey
Legislative Attorney

Suzanne M. Kirchhoff
Analyst in Health Care Financing

Hannah-Alise Rogers
Legislative Attorney

The 2022 budget reconciliation legislation commonly known as the Inflation Reduction Act (IRA; P.L. 117-169) established the Medicare Drug Price Negotiation Program (Program). The Program authorizes the Secretary of Health and Human Services (Secretary) to negotiate prices for certain single-source chemical drugs and biological products under Medicare Part B (physician-administered drugs) or Part D (retail prescription drugs). Among other requirements, to qualify for selection by the Program, a chemical drug (a.k.a. "small-molecule" drug) must have had Food and Drug Administration (FDA) approval for at least 7 years, and a biological product must have been FDA-licensed for at least 11 years. The negotiated prices are subject to a ceiling known as the maximum fair price (MFP).

In accordance with the statute, the Secretary must negotiate MFPs for 10 drugs to take effect in 2026, 15 additional drugs for 2027 and 2028, and 20 additional drugs for 2029 and each following year. In 2026 and 2027, the Program applies only to Part D drugs.

In August 2023, the Department of Health and Human Services (HHS) selected the first 10 Part D drugs for negotiation under the Program. In October 2023, HHS announced that manufacturers of all 10 drugs had agreed to participate in negotiations with the Secretary.

Even as manufacturers participate in the negotiations, several have filed lawsuits challenging both the constitutionality of the Program and its implementation by the Centers for Medicare & Medicaid Services (CMS). Stakeholders are also asking Congress to alter certain provisions of the IRA that they assert will harm pharmaceutical research and development and undercut current patent and marketing protections.

This report provides information related to several topics of recent congressional interest with respect to the implementation of the IRA, including litigation surrounding the Program; concerns about its impact on future drug innovation, research, and development; and questions about its interaction with patents and other federal marketing protections for pharmaceuticals.

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This report provides information related to several topics of recent congressional concern with respect to the implementation of the prescription drug negotiation provisions of the 2022 budget reconciliation legislation commonly known as the Inflation Reduction Act (IRA; P.L. 117-169),[1] including litigation surrounding the Medicare Drug Price Negotiation Program (Program); concerns about its impact on future drug innovation, research, and development; and questions about its interaction with patents and other federal marketing protections for pharmaceuticals.

Medicare Coverage of Prescription Drugs

The federal Medicare program pays for covered health care services of qualified beneficiaries, including prescription drugs.[2] Medicare Part A covers inpatient hospital services, skilled nursing care, hospice care, and some home health services. Part A typically pays providers for drugs as part of a predetermined, per-episode payment. Medicare Part B covers physician care, outpatient services, and some home health and preventive services. Medicare pays most health care practitioners for Part B prescription drugs based on a statutory formula, which is the drug's average sales price (ASP) plus a percentage add-on payment.[3]

Medicare Part D is a voluntary benefit that provides coverage of outpatient prescription drugs to beneficiaries who enroll in stand-alone private prescription drug plans (PDPs) or Medicare Part C (Medicare Advantage, or MA) managed care plans (which cover Part A hospital coverage and B services) with a Part D component (MA-PDs).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003[4] (MMA), which created the Part D program, included a "noninterference" provision that barred the Health and Human Services (HHS) Secretary (the Secretary) from negotiating Part D prices, requiring a set formulary (list of covered drugs), or pricing structure.[5] Instead, Part D plan sponsors (insurers), working with pharmacy benefit managers (PBMs), negotiate prescription drug price discounts and rebates with pharmaceutical manufacturers and dispensing pharmacies.[6]

Overall, Medicare accounts for about 32% of U.S. retail drug spending, with much of the spending concentrated in higher-cost brand name and specialty drugs.[7]

[1] Pub. L. No. 117-169, tit. I, subtit. B, pt. 1, 136 Stat. 1818, 1833–464 (2022) (codified at 42 U.S.C. §§ 1320f-1 to f-7 and 26 U.S.C. § 5000D).

[2] CRS Report R40425, *Medicare Primer*, coordinated by Patricia A. Davis (2020).

[3] For the ASP methodology, *see* 42 U.S.C. § 1395w-3a.

[4] Pub. L. No. 118-173 (2003).

[5] 42 U.S.C. § 1395w-111(i).

[6] For more information about PBMs, their role in the prescription drug market, and federal and state regulations over them, *see* CRS Legal Sidebar LSB11080, *Pharmacy Benefit Managers: Current Legal Framework*, by Hannah-Alise Rogers, Jennifer A. Staman, and Alexander H. Pepper (2023).

[7] HHS, *National Health Expenditure Data, Projected*, Downloads, *NHE Projections-Tables*, tbl. 11 (Sept. 6, 2023), https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected. The NHE figures do not include Medicare-covered drugs dispensed as a part of a hospital stay. For the Medicare Part D program, specialty drugs are defined as those that cost more than $830 per year in 2023. Private health plans may have their own definition of *specialty drug* based on factors in addition to cost, such as difficulty in handling and administration.

Selected Drug Negotiation Provisions of the IRA

Drugs Eligible for Negotiation

The IRA requires the Secretary to negotiate prices for certain single-source chemical drugs and biologics[8] covered under Medicare Parts D and B. To be selected for negotiation, a chemical drug cannot have a marketed generic substitute and must have been approved by FDA for at least 7 years, while a biologic cannot have a marketed biosimilar substitute and must have been licensed by the Food and Drug Administration (FDA) for at least 11 years. In addition, the product must be among the 50 qualifying single-source drugs with the highest gross spending in Part B or Part D.

The Secretary must negotiate maximum fair prices (MFPs) for 10 drugs to take effect in 2026, 15 additional drugs for each of 2027 and 2028, and 20 additional drugs for 2029 and each following year. For the first two years (2026 and 2027), the Program applies only to Part D drugs.

The IRA excludes the following drugs from negotiation:

- low-spend drugs (i.e., drugs with Medicare spending of less than $200 million; indexed for inflation in subsequent years);
- plasma-derived products;
- orphan drugs designated for only one rare disease and for which the only FDA-approved indication is for such disease;[9] and
- certain products made by small biotech firms (through 2028).[10]

The Secretary may delay negotiation of qualifying biologic products for up to two years when the Secretary determines that there is a high likelihood that a biosimilar will soon enter the market.[11]

In August 2023, HHS announced the first 10 drugs selected for negotiation under the Program, with negotiated prices to become effective in 2026.[12] (See **Table 1**.) In October 2023, the

[8] *Biologics* are pharmaceuticals derived from a living organism, *see* 42 U.S.C. § 262(i)(1), that can be many times the size of a conventional (small-molecule or chemical) drug and have a more complex structure. A *biosimilar* is a follow-on to a biologic that is "highly similar," notwithstanding minor differences in clinically inactive components. *Id.* § 262(k)(2)(A). There are no clinically meaningful differences between a biosimilar and the reference biologic product in terms of safety, purity, and potency of the product. *Id.* § 262(k)(2)(b). The Patient Protection and Affordable Care Act (ACA) provided a period of exclusivity for manufacturers of certain biologic brand-name drugs and biosimilar products. *See* Pub. L. No. 111-148, tit. VII, subtit. A, § 7002 (codified at 42 U.S.C. § 262(k)(7)).

[9] For more information about the Orphan Drug Act (ODA), *see* CRS Report R47653, *The Orphan Drug Act and Catalyst Pharmaceuticals, Inc., v. Becerra*, by Hannah-Alise Rogers (2023). The ODA covers drugs intended to treat rare conditions, generally defined as those affecting fewer than 200,000 people in the United States, or those affecting more than 200,000 people but for which there is no reasonable expectation that the costs of developing the drug will be recouped in the United States. 21 U.S.C. § 360bb. Under the ODA, an orphan drug may be indicated for use in multiple diseases or conditions. The IRA's orphan drug exception is thus not inclusive of all orphan drugs.

[10] *See* 42 U.S.C. § 1320f-1(d)(2).

[11] 42 U.S.C. § 1320f-1(f).

[12] Press Release, HHS, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026 (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html; ASPE INFLATION REDUCTION ACT RESEARCH SERIES FACT SHEET NO. HP-2023-21: *Medicare Enrollees' Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price Negotiation Program* (Sept. 2023). CMS was required to choose the 10 drugs from the negotiation-eligible pool of 50 qualifying drugs based on their total spending rank.

Secretary announced that all manufacturers of the selected drugs had agreed to participate in negotiations.[13]

Table 1. Part D Selected Drugs for Negotiation for the Initial 2026 Price Year

Drug Name	Manufacturer	Drug Indication	Total Part D Gross Drug Spending from June 2022–May 2023	Number of Enrollees Using Drug from June 2022–May 2023
Eliquis (apixaban)	Bristol Myers Squibb Partner: Pfizer	Prevention and treatment of blood clots	$16,482,621,000	3,706,000
Jardiance (empagliflozin)	Boehringer Ingelheim Partner: Eli Lilly	Diabetes; Heart failure	$7,057,707,000	1,573,000
Xarelto (rivaroxaban)	Janssen Pharmaceuticals (Johnson & Johnson)	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	$6,031,393,000	1,337,000
Januvia (sitagliptin phosphate)	Merck Sharp Dohme	Diabetes	$4,087,081,000	869,000
Farxiga (dapagliflozin)	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	$3,268,329,000	799,000
Entresto (sacubitril valsartan)	Novartis Pharmaceuticals Corp.	Heart failure	$2,884,877,000	587,000
Enbrel (etanercept)	Immunex Corp (Amgen)	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	$2,791,105,000	48,000
Imbruvica (ibrutinib)	Pharmacyclics LLC (Abbvie)	Blood cancers	$2,663,560,000	20,000
Stelara (ustekinumab)	Janssen Biotech, Inc. (Johnson & Johnson)	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	$2,638,929,000	22,000
Fiasp[a] (insulin aspart)	Novo Nordisk Inc.	Diabetes	$2,576,586,000	777,000

Source: Press Release, HHS, HHS Selects the First Drugs for Medicare Drug Price Negotiation, (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/10/03/biden-harris-administration-moves-medicare-drug-price-negotiations-lower-prescription-drug-costs-people-medicare.html; CMS, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026 (Aug. 2023), https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf.

Notes: According to HHS, from June 1, 2022 to May 31, 2023 (the time period used to determine which drugs were eligible for negotiation), about 8.3 million Part D enrollees used these drugs. The selected drugs accounted for $50.5 billion in total Part D gross covered prescription drug costs, or about 20% of total Part D gross covered prescription drug costs during that period.

[13] Press Release, HHS, Biden-Harris Administration Moves Forward with Medicare Drug Price Negotiations to Lower Prescription Drug Costs for People with Medicare (Oct. 3, 2023), https://www.hhs.gov/about/news/2023/10/03/biden-harris-administration-moves-medicare-drug-price-negotiations-lower-prescription-drug-costs-people-medicare.html.

Enbrel, Stelara, and Fiasp are biologics.

a. The designation also covers the products FiaspFlexTouch, Fiasp PenFill, NovoLog, NovoLog FlexPen, and NovoLog PenFill.

MFP Ceiling

The Secretary and manufacturers are to engage in negotiations on MFPs for the first round of selected drugs from October 1, 2023, to August 1, 2024. During the negotiation period, the Secretary will consider factors including each manufacturer's research and development (R&D) costs for the drug, production cost, any federal financial support for development of the drug, and data on patents and existing and pending exclusivities. The Secretary is to publish the negotiated MFPs for 2026 no later than September 1, 2024. Each subsequent year under the Program, MFPs are to take effect two years after new drugs are selected for negotiation.

The IRA sets a ceiling on the MFP, based on the lesser of

1. the weighted average net price of the drug or biologic under Part D (and starting in 2028, average Part B prices);[14] or
2. a percentage of the nonfederal average manufacturer price (non-FAMP). The non-FAMP is a wholesaler price, minus certain discounts, that is used in calculating a maximum price for drugs by the "big four" federal purchasers: the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard. The MFP ceiling is 75% of the non-FAMP for a drug approved for less than 16 years or 40% of the non-FAMP for a drug approved for 16 years or more.[15]

An MFP is calculated across all dosage forms and strengths of a drug and is in effect until the first year beginning at least nine months after a generic or biologic substitute for a drug is marketed.

Manufacturers that do not comply with the Program could be subject to a civil monetary penalty or an excise tax. The excise tax would be set as a percentage of the sum of the drug's sales price plus the excise tax imposed by the IRA. This percentage could range from 65% up to a maximum of 95%, if a manufacturer were out of compliance more than 270 days.[16]

Industry Responses to IRA Negotiation Program

Even though all the manufacturers of selected drugs for 2026 agreed to enter into negotiations with the Secretary, several manufacturers and other stakeholders have sued the government to strike down or alter the IRA negotiation provisions as unconstitutional.[17] Industry representatives, patient advocates, and other stakeholder groups have also asked Congress and the Centers for Medicare & Medicaid Services (CMS) to alter certain provisions of the statute or update regulatory guidance for implementing the law. Industry and patient advocacy groups have sought

[14] For Part B drugs, the average price is the ASP from the previous year. For Part D, the average price is based on data form the most recent year available.

[15] Starting in 2030, the IRA includes a third MFP ceiling, which is to be 65% of the non-FAMP for a selected drug that has been approved or licensed for at least 12 years but fewer than 16 years.

[16] Section 11003 of the IRA amended IRC Subtitle D to add a new Section 5000D, containing the excise tax. *See* 26 U.S.C. § 5000D.

[17] *See, e.g.*, Complaint, Merck & Co. v. Becerra, No. 23-1616 (D.D.C. Jun. 6, 2023), ECF No. 1.

changes to two aspects of the IRA in particular: (1) its treatment of orphan drugs, and (2) its different timelines for the negotiation of drugs versus biologics.[18]

Orphan Drug Provisions

The IRA exempts from the Program orphan drugs used to treat only one rare disease or condition and for which the only approved indication (or indications) is for such disease or condition.[19] In addition, drugs with an annual Medicare cost of less than $200 million are exempt from negotiation, a provision that could shield some orphan products from negotiation.

Some stakeholders have expressed concern that the orphan drug exemption is insufficient and could deter innovation, especially for existing approved orphan products.[20] At least one manufacturer has also challenged CMS's interpretation of "qualifying single source drug" as it applies to the IRA's orphan drug exception.[21]

Federal law provides tax breaks and extended marketing exclusivity for developers of orphan drugs, and the majority of all novel drugs approved by FDA in the past several years have been orphan products.[22] Orphan drug manufacturers may seek orphan drug approval of a new indication for an already-approved orphan drug or an already-approved nonorphan drug, allowing use for more than one condition.[23]

Although orphan drugs are intended to serve small patient populations or conditions for which therapies are not expected to be profitable, a recent report from the HHS Office of Inspector General found that a majority of 40 high-spending Medicare drugs it studied had orphan-drug designations, including drugs initially approved to treat common conditions.[24]

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[18] *See, e.g.,* Press Release, PhRMA, New Analysis: Inflation Reduction Act Undermines Cancer Medicine Development, (June 1, 2023), https://phrma.org/resource-center/Topics/Access-to-Medicines/New-Analysis-Inflation-Reduction-Act-Undermines-Cancer-Medicine-Development and Kevin Dunleavy, *Pfizer CEO Bourla Slams Medicare IRA Measure as "Negotiation with a Gun to Your Head*", FIERCE PHARMA (May 12, 2023), https://www.fiercepharma.com/pharma/pfizer-ceo-bourla-calls-medicare-ira-measure-negotiation-gun-your-head.

[19] CMS, MEDICARE DRUG PRICE NEGOTIATION PROGRAM: REVISED GUIDANCE, IMPLEMENTATION OF SECTIONS 1191 – 1198 OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2026, (2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf [hereinafter CMS REVISED GUIDANCE]. Under 42 U.S.C. § 1320f-1(e)(3)(A), to meet the definition of *orphan drug* for purposes of exclusion as a qualifying single source drug, a drug must (1) be designated under Section 526 of the Food, Drug, and Cosmetics Act as a drug used to treat only one rare disease or condition; and (2) be FDA-approved to treat only one indication (or indications) associated with that condition.

[20] Letter from National Organization for Rare Disorders, to Chiquita Brooks-LaSure, Administrator CMS & Meena Seshamani, Deputy Administrator (Apr. 24, 2023), https://rarediseases.org/wp-content/uploads/2023/04/Final_NORD_comments_MDPNP.pdf.

[21] Amended Complaint, AstraZeneca Pharms. v. Becerra at 30, No. 23-0931 (D. Del. Aug. 25, 2023), ECF No. 16. For more information about this claim, see "Legal Challenges."

[22] For example, in 2022, 54% of new drug approvals were orphan drugs. FDA Center for Drug Evaluation and Research, *New Drug Therapy Approvals 2022* (Jan. 10, 2023), https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2022.

[23] S. Sean Tu, et al., *Five-Year Sales for Newly Marketed Prescription Drugs With and Without Initial Orphan Drug Act Designation*. JAMA (May 9, 2023), https://jamanetwork.com/journals/jama/fullarticle/2804613.

[24] HHS Office of the Inspector General, *High-expenditure Medicare drugs often qualified for Orphan Drug Act incentives designed to encourage the development of treatments for rare diseases* (Sept. 28, 2021), OEI-BL-20-00080, https://oig.hhs.gov/oei/reports/OEI-BL-20-00080.asp.

CMS is considering additional actions in its implementation of the Program to support orphan drug development, including considering a drug's impact on unmet medical need and on specific populations during negotiations with manufacturers to set a final MFP.[25]

IRA Timelines for Selection of Chemical and Biologic Products

Existing federal law provides for disparate treatment of chemical and biological products in many ways. (See "Drug Patent and Marketing Protections.") Even so, some pharmaceutical firms and investors have questioned the rationale for having different timelines for negotiating MFPs for chemical and biologic prescription products, saying it will make chemical drugs less financially attractive for investment.[26]

The final version of the IRA was developed in negotiations outside the formal committee process, so there is limited public legislative history of the timeline provision. Congress debated drug price negotiation bills before the IRA that did not distinguish between chemical and biological products or set time-on-market requirements for negotiation eligibility. In 2019, the House passed H.R. 3, which would have required the Secretary to negotiate MFPs for insulins and single-source drugs and biologics that were FDA approved or licensed, were still marketed, and were among the 125 drugs with the estimated highest net spending in Medicare Part D or in the United States. New drugs likely to meet high-spending criteria were negotiation-eligible immediately following approval or licensure.

In September 2021, the House Ways and Means Committee approved drug negotiation provisions as part of the FY2023 reconciliation measure known as the Build Back Better Act (BBBA) that largely tracked H.R. 3 from 2019.[27] The Energy and Commerce Committee did not advance the provisions after three majority Members voted "no," concerned that the bill would weaken incentives for drug development.[28] During the Energy and Commerce markup, Representative Scott Peters raised but withdrew an amendment based on bills (H.R. 5260 and H.R. 5237) to allow the Secretary to negotiate prices only for single-source Medicare Part B drugs where federal marketing and patent protection had expired.[29]

In November 2021, the House approved a revised version of the BBBA (H.R. 5376) which specified that MFPs could not apply until 9 years after approval for chemical drugs, or 13 years after licensure for biologics. In August 2022, Congress passed the final version of the IRA, which had these provisions as well.

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[25] CMS REVISED GUIDANCE, *supra* note 19, § 60.3.

[26] *See, e.g.*, Daniel Skovronsky, *The IRA's Nonsensical Distinction between Small- and Large-molecule Drugs*, STAT (May 9, 2023), https://www.statnews.com/2023/05/09/ira-inflation-reduction-act-small-large-molecule-drugs/.

[27] The House Ways and Means Committee drug negotiation provisions were in Subtitle J of the committee draft of the Build Back Better Act. *See* Press Release, House Ways and Means Committee Democrats, Chairman Neal Announces Additional Day of Markup of the Build Back Better Act (Sept. 10, 2021), https://democrats-waysandmeans.house.gov/media-center/press-releases/chairman-neal-announces-additional-day-markup-build-back-better-act. The House Energy and Commerce Committee considered the drug pricing provision in Subtitle E of the committee draft bill. *See Markup of the Build Back Better Act, Full Committee*, H. ENERGY AND COMMERCE COMM. DEMOCRATS, (Sept. 13, 2021), https://democrats-energycommerce.house.gov/committee-activity/markups/markup-of-the-build-back-better-act-full-committee-september-13-2021.

[28] Alice Miranda Ollstein and Sarah Ferris, *Centrist Democrats Scramble House Drug Pricing Effort*, POLITICO (Sept. 15, 2021), https://www.politico.com/news/2021/09/15/centrist-democrats-drug-pricing-511955.

[29] Rep. Scott Peters, *Don't Slow Research on Promising Drugs*, REP. SCOTT PETERS (Sept. 29, 2021), https://scottpeters.house.gov/2021/9/dont-slow-research-on-promising-drugs.

Legal Challenges

Drug manufactures have challenged the Program on a number of legal grounds, making its ultimate implementation uncertain. In the various lawsuits, the government has attempted to refute manufacturers' claims that the IRA will significantly change the drug industry, that the negotiation of the MFPs will ultimately decrease revenues, and that manufacturers will be discouraged from investing in research and development for new drugs.[30]

At least seven pharmaceutical manufacturers and two trade associations have filed lawsuits against CMS, arguing that the IRA is unconstitutional.[31] The plaintiffs claim that the IRA violates the First Amendment because it compels speech,[32] and that it violates the Fifth Amendment Due Process and Takings Clauses.[33] A few plaintiffs also claim that the excise tax violates the Eighth Amendment Excessive Fines Clause,[34] and that various provisions of the IRA violate the Nondelegation Doctrine.[35] The plaintiffs also argue that the IRA cannot be justified under Congress's Spending Clause power because it does not condition Medicare reimbursement on participation in the Program and that it is unconstitutionally coercive.[36]

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[30] *See, e.g.*, Defendant's Motion to Dismiss at 16–19, Dayton Area Chamber of Com., et al. v. Becerra, No. 23-0156 (S.D. Ohio Aug. 11, 2023), ECF No. 33 [hereinafter Chamber of Com. Mot. to Dismiss].

[31] Complaint, Merck & Co. v. Becerra, No. 23-1615 (D.D.C. Jun. 6, 2023), ECF No. 1 [hereinafter Merck Compl.]; Complaint, Dayton Area Chamber of Com., et al. v. Becerra, No. 23-0156 (S.D. Ohio, Jun. 9, 2023), ECF No. 1 [hereinafter Chamber of Com. Compl.]; Complaint, Bristol Myers Squibb Co. v. Becerra, No. 23-3335 (D.N.J. Jun. 16, 2023), ECF No. 1 [hereinafter Bristol Myers Compl.]; Complaint, Pharm. Rsch. & Mfrs. of Am. (PhRMA) et al. v. Becerra, No. 23-0707 (W.D. Tex. Jun. 21, 2023), ECF No. 1 [hereinafter PhRMA Compl.]; Complaint, Janssen Pharms. Inc. v. Becerra, No. 23-3818 (D.N.J. July 18, 2023), ECF No. 1 [hereinafter Janssen Compl.]; Complaint, Astellas Pharma U.S., Inc. v. Becerra, No. 23-4578 (N.D. Ill. July 14, 2023), ECF No. 1 [hereinafter Astellas Compl.]; Complaint, Boehringer Ingelheim Pharms., Inc., v. Becerra, No. 23-01103 (D. Conn. Aug. 18, 2023), ECF No. 1 [hereinafter Boehringer Compl.]; Amended Complaint, AstraZeneca Pharms. LP v. Becerra, No. 23-0931 (D. Del. Sept. 26, 2023), ECF No. 16 [hereinafter AstraZeneca Amend. Compl.]; Complaint, Novartis Pharms. Corp. v. Becerra, No. 23-14221, (D.N.J. Sept. 1, 2023), ECF No. 1 [hereinafter Novartis Compl.]; Complaint, Novo Nordisk, Inc. v. Becerra, No. 23-20814, (D.N.J. Sept. 29, 2023), ECF No. 1 [hereinafter Novo Nordisk Compl.].

[32] *See, e.g.*, Merck Compl. at 3; Chamber of Com Compl. at 8; Bristol Myers Compl. at 20; Janssen Compl. at 6; Astellas Compl. at 4; Boehringer Compl. at 6.

[33] All of the plaintiffs argue that the IRA violates some provision of the Fifth Amendment, with some claiming Due Process Clause violations, and others claiming Takings Clause violations. *E.g.*, Chamber of Com. Compl. at 40; PhRMA Compl. at 6; Merck Compl. at 15; Bristol Myers Compl. at 26. For more information about the Fifth Amendment Due Process Clause, *see* Cong. Research Serv., *Amt. 5.7.1, Overview of Substantive Due Process*, Constitution Annotated, available at https://constitution.congress.gov/browse/essay/amdt5-7-1/ALDE_00013728/ (last accessed Dec. 4, 2023). For more information about the Fifth Amendment Takings Clause, *see* Cong. Research Serv., Amt. 5.9.1, *Overview of Takings Clause*, available at https://constitution.congress.gov/browse/essay/amdt5-9-1/ALDE_00013280/ (last accessed Dec. 4, 2023).

[34] *E.g.*, Chamber of Com. Compl. at 47; PhRMA Compl. at 55; Boehringer Compl. at 39.

[35] For an overview of the Nondelegation Doctrine, *see* Cong. Research Serv., *Art. I, S.1.5.1 Overview of Nondelegation Doctrine*, Constitution Annotated, available at https://constitution.congress.gov/browse/essay/artI-S1-5-1/ALDE_00000014/#ALDF_00016513 (last accessed Dec. 7, 2023). For more information on the Nondelegation doctrine and its history, *see* Cong. Research Serv., *Art. I, S.1.5.2 Historical Background on Nondelegation Doctrine*, Constitution Annotated, available at https://constitution.congress.gov/browse/essay/artI-S1-5-2/ALDE_00000009/ (last accessed Dec. 7, 2023).

[36] *E.g.*, Bristol Myers Compl. at 24; Merck Compl. at 22; Janssen Compl. at 6; Boehringer Compl. at 42. For more information on the constitutional claims made by the plaintiffs, *see* CRS Report R47682, *Constitutional Challenges to the Medicare Drug Price Negotiation Program*, by Hannah-Alise Rogers (2023). For more information on Congress's authority under the Spending Clause, *see* Cong. Research Service, *Art. I S.8.C1.2.1 Overview of Spending Clause*, Constitution Annotated, available at https://constitution.congress.gov/browse/essay/artI-S8-C1-2-1/ALDE_00013356/ (last accessed Dec. 7, 2023); *see also* CRS Report R46827, *Funding Conditions: Constitutional Limits on Congress's Spending Power*, by Victoria L. Killion (July 1, 2021).

At least two pharmaceutical manufacturer plaintiffs have also claimed that CMS's implementation of the Program violates the Administrative Procedure Act (APA). Although the statute requires CMS to implement the Program via agency guidance, the manufacturers claim that the guidance violates the APA because parts of it were finalized without stakeholder input.[37] Manufacturers argue that the guidance should have been promulgated as a legislative rule, as it legally binds manufacturers and will subject them to steep penalties for noncompliance.[38] Another manufacturer argues that CMS's guidance "override[s]" the IRA's definition of "qualifying single source drug" by making it overly broad, so as to include more than one drug.[39] They also dispute CMS's "bona fide marketing" requirement, arguing that this could make a drug eligible for selection even if it has market competition.[40]

At least one manufacturer has challenged CMS's interpretation of the IRA's orphan drug exclusion provision. The manufacturer argues that although the IRA excludes some orphan drugs from price negotiation,[41] CMS's guidance aggregates drugs and biologics with the same active ingredient, such that the orphan drug exclusion will apply only if the entire group of products with the same active moiety is approved to treat a single orphan disease.[42]

The government has filed at least one motion to dismiss,[43] and summary judgment motions have been filed by both the plaintiffs and the government in several of the cases,[44] which could fast track decisions in the cases. Some observers expect that at least one of the cases will eventually reach the U.S. Supreme Court.[45] The lawsuits have not yet interfered with CMS's implementation of the Program. For example, in September 2023, an Ohio district court denied a motion for a preliminary injunction to halt temporarily CMS's implementation of the Program, finding that the plaintiffs had not presented sufficient evidence that they would prevail on the merits of their constitutional arguments.[46] It could take years for all of the cases to be finally resolved, and the outcome of the litigation will determine how effectively CMS will be able to carry out the Program and uphold the Program's stated goals of lowering prescription drug prices for Medicare.

Drug Patent and Marketing Protections

Some industry concerns involve the potential impact of the Program on existing patent and marketing protections for pharmaceuticals.

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[37] AstraZeneca Amend. Compl. at 22. Note that several other plaintiffs allege that the lack of stakeholder input violates the Fifth Amendment Due Process Clause. *See, e.g.*, Chamber of Com. Compl. at 40.

[38] Chamber of Com. Compl. at 40.

[39] AstraZeneca Amend. Compl. at 7.

[40] *Id.* at 17; *see also* Novo Nordisk Compl. at 39.

[41] *See* 42 U.S.C. § 132-f-1(e)(3)(A); CMS REVISED GUIDANCE, *supra* note 19, § 30.1.1.

[42] AstraZeneca Amend. Compl. at 30.

[43] *See, e.g.*, Defendant's Mot. to Dismiss, Dayton Area Chamber of Com., et al. v. Becerra, No. 23-0156 (S.D. Ohio, Jun. 9, 2023), ECF No. 33. On September 29, 2023, the court denied the government's motion to dismiss. Order, Dayton Area Chamber of Com., et al. v. Becerra, ECF No. 55.

[44] *See, e.g.*, Plaintiff's Mot. for Summary Judgment, Merck & Co. v. Becerra, No. 23-1615, (D.D.C. July 11, 2023), ECF No. 23; Defendant's Cross Mot. for Summary Judgment & Opposition to Plaintiff's Mot. for Summary Judgment, Merck & Co. v. Becerra, No. 23-1615 (D.D.C. Sept. 11, 2023), ECF No. 24; Plaintiff's Mot. for Summary Judgment, AstraZeneca Pharms. LP v. Becerra, No. 23-0931 (D. Del. Sept. 26, 2023), ECF No. 18; Defendant's Cross Mot. for Summary Judgment, AstraZeneca Pharms. LP v. Becerra, No. 23-0931 (D. Del. Nov. 1, 2023), ECF No. 21.

[45] Ian Lopez, *Drugmakers Prep Medicare Pricing Suits for March to High Court*, BLOOMBERG LAW (Aug. 17, 2023).

[46] Order Denying Plaintiffs' Motion for Preliminary Injunction, Dayton Area Chamber of Com., et al. v. Becerra, No. 23-0156, (S.D. Ohio Sept. 29, 2023), ECF No. 55.

New drugs and biologics are typically protected from generic and biosimilar competition by two distinct forms of intellectual property (IP) protection.[47] To encourage innovation, patents grant inventors the exclusive right to make and sell a novel invention.[48] Many innovations relating to a pharmaceutical product (such as the active ingredient, particular formulations, manufacturing processes, or methods of using a drug against particular diseases) may be patented.[49] Patents typically expire 20 years after the filing date of the relevant patent application.[50]

Similarly, the FDA grants regulatory exclusivities to innovative pharmaceuticals meeting certain criteria.[51] During a period of regulatory exclusivity, the FDA cannot approve applications for a generic or biosimilar form of the product.[52] The main regulatory exclusivity for new chemical drugs lasts 5 years,[53] and the main exclusivity for new biologics lasts 12 years.[54] There are also a number of more specific exclusivities (such as the seven-year orphan drug exclusivity) that may apply to a particular product.[55]

By design, both patents and regulatory exclusivities may enable drug manufacturers to charge higher-than-competitive prices because the product is protected from generic and biosimilar competition while these rights are in effect.[56] IP rights are typically justified as necessary to encourage innovation and for manufacturers to recoup their R&D costs, but are sometimes criticized as contributing to high prices for pharmaceutical products.[57] For example, some stakeholders and Members of Congress have questioned particular patenting strategies—such as "product hopping," "evergreening," and "patent thickets"—that allegedly misuse the IP system to unduly extend the periods of exclusivity for particular drugs and biologics.[58]

Precisely when generic or biosimilar competition occurs for any given product depends on a complex interplay of market incentives, patents, regulatory exclusivities, FDA processes, and—not infrequently—litigation.[59] Although patents can last up to 20 years, some of the patent term is taken up by the patent application process itself. Still more of a patent's term may also occur prior to market approval for a drug or biologic, particularly for patents granted early in a product's life cycle, such as active-ingredient patents.[60] In addition, although patents carry a presumption of

[47] *See generally* CRS Report R46679, *Drug Prices: The Role of Patents and Regulatory Exclusivities*, coordinated by Erin H. Ward (2021).

[48] 35 U.S.C. § 271; *see generally* Cong. Rsch. Serv, *ArtI.S8.C8.1 Overview of Congress's Power Over Intellectual Property*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C8-1/ALDE_00013060/ (last accessed Dec. 7, 2023).

[49] Ward, *supra* note 47, at 24–26.

[50] 35 U.S.C. § 154(a)(2).

[51] *See generally* CRS In Focus IF11217, *Drug Pricing and the Law: Regulatory Exclusivities*, by Erin H. Ward (2019).

[52] *Id.*

[53] *See* 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).

[54] *See* 42 U.S.C. § 262(k)(7).

[55] *See* Ward, *supra* note 51.

[56] *See* Ward, *supra* note 47, at 4.

[57] *Id.* at 2.

[58] *See generally* CRS In Focus IF11561, *Pharmaceutical Patenting Practices: A Legal Overview*, coordinated by Kevin J. Hickey (2020).

[59] *See id.*

[60] *See generally* Aaron S. Kesselheim et al., *Determinants of Market Exclusivity for Prescription Drugs in the United States*, 177 JAMA INTERNAL MED. 1658, 1658–59 (2017), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2653014. Patent term extensions may compensate for lost effective exclusivity period consumed by regulatory review. *See* 35 U.S.C. § 156.

validity,[61] they may be challenged by generic and biosimilar manufacturers in court.[62] In practice, empirical studies usually find that the average effective market exclusivity period for new drugs (i.e., the average time before actual generic entry) is between 12 and 15 years.[63] Although data are limited, some studies show that average effective exclusivity periods are longer for biologics.[64] This difference may be due to patenting factors[65] and to the longer general regulatory exclusivity period (12 years) for new biologics.[66]

Potential Effects of the IRA on the Pharmaceutical Market

In theory, the provisions of the IRA could alter some economic incentives in the pharmaceutical industry. As a result, the industry may respond with changes to its product development, patent acquisition, and patent assertion practices. Whether and how much such changes occur is uncertain, as this will depend on many factors, including how the Program is implemented.

Potential Effects of the Program on R&D Incentives

First, according to some analyses, price negotiation under the IRA could reduce the overall revenue for selected brand-name products, because negotiation limits the power to set prices for the Medicare market.[67] Presuming a chemical drug is selected for negotiation and has an average effective exclusivity of 13 years, the price-setting power afforded by its patent monopoly will be

[61] *See* Microsoft Corp. v. i4i Ltd., 564 U.S. 91, 95 (2011).

[62] *See* CRS In Focus IF11214, *Drug Pricing and the Law: Pharmaceutical Patent Disputes*, by Kevin J. Hickey (2019).

[63] *See* Henry Grabowski et al., *Continuing Trends in U.S. Brand-name and Generic Drug Competition*, 24 J. MED. ECON. 908, 908 (2021) (finding average market exclusivity period of 14.1 years for all drugs with generic entry between 2017 and 2019, and an average of 13 years for drugs with sales over $250 million); Benjamin N. Rome et al., *Market Exclusivity Length for Drugs with New Generic or Biosimilar Competition, 2012–2018*, 109 CLINICAL PHARM & THERAPEUTICS 367 (2020) (finding average market exclusivity of 14.4 years); Erika Lietzan & Kristina M.L. Acri née Lybecker, *Distorted Drug Patents*, 95 WASH. L. REV. 1317, 1363 (2020) (finding an average effective market exclusivity period of 12.6 years for drugs with restored patent terms under the Hatch-Waxman Act); Henry Grabowski et al., *Updated Trends in U.S. Brand-Name and Generic Drug Competition*, 19 J. MED. ECON. 836, 836 (2016) (finding average effective exclusivity period of 13.6 years for all drugs with generic entry between 1995 and 2014, and an average of 12.5 years for drugs with sales over $250 million); Bo Wang et al., *Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States*, 175 JAMA INTERNAL MED. 635, 636 (2015) (finding an average effective market exclusivity of 12.5 years for top-selling drugs between 2000 and 2012); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 336 (2012) (finding an average market exclusivity of 12.2 years that was "stable" over the decade studied).

[64] *See* Rome et al., *supra* note 63, at 368 (finding average effective market exclusivity of 21.56 years for the four biologics in the study).

[65] *See* Hickey, *supra* note 58.

[66] 42 U.S.C. § 262(k)(7).

[67] *See* DANA GOLDMAN ET AL., MITIGATING THE INFLATION REDUCTION ACT'S ADVERSE IMPACTS ON THE PRESCRIPTION DRUG MARKET 4 (April 2023), https://healthpolicy.usc.edu/wp-content/uploads/2023/04/2023.04_Schaeffer-White-Paper_Mitigating-Adverse-Impacts-of-the-IRA.pdf ("The IRA is expected to reduce revenue to pharmaceutical manufacturers from the combined effects of drug price negotiation, inflation rebates, and required manufacturer discounts."); TOMAS J. PHILIPSON & TROY DURIE, ISSUE BRIEF: THE IMPACT OF H.R. 5376 ON BIOPHARMACEUTICAL INNOVATION AND PATIENT HEALTH (2021), https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf (estimating hundreds of billions of lost pharmaceutical industry revenue due to price negotiations); *but see* Annika Kim Constantino, *Medicare Drug Price Negotiations May Have a Muted Impact in the Near Term*, CNBC (Aug. 30, 2023) ("[A]nalysts say the drug price talks will likely have a muted financial impact on manufacturers, at least for this first round of prescription medicines.").

somewhat weaker in years 9 through 13 if selected for negotiation under the Program.[68] Put another way, although Medicare participants may benefit from lower prices under the Program, negotiation arguably reduces overall incentives to invest in new product development.[69] On the other hand, it is not clear whether this effect will be practically significant because, among other things, it is unclear how much negotiation will affect manufacturers' revenue,[70] and it is difficult to predict whether a drug still in development will be subject to negotiation years later. Some may also view existing incentives (including patents and regulatory exclusivities) as sufficient to encourage investment in R&D, and question whether selection of a small class of drugs for negotiation meaningfully alters those incentives.[71]

Second, because chemical drugs are subject to price negotiation earlier than biologics, the IRA could make biologics development comparatively more attractive for investment.[72] (This difference may already be true to some degree, given the longer exclusivity period for biologics and the generally weaker effect of biosimilar competition on prices as compared to generic competition.[73]) For example, a 2022 survey by Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group for the drug industry, found 63% of responding member companies planned to shift R&D focus away from small molecules in response to the IRA and 95% to develop fewer uses for new medicines.[74] Whether this effect will be significant in practice remains to be seen, and other factors (such as the potential market for a product) may be more significant in R&D decisions than the possibility of MFPs imposed no earlier than 9 or 13 years after approval or licensure.[75]

Third, because only single-source products are subject to negotiation, brand-name manufacturers may have reduced incentives to litigate generic and biosimilar entry, at least on the margins. Especially for biologics, a brand manufacturer could prefer in some cases to allow biosimilar competition to avoid being subject to price negotiation.[76] While brand-name manufacturers generally seek to prevent competition, immunity from price negotiation may influence the cost-

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[68] *See* Rachel Sachs et al., *A Holistic View of Innovation Incentives and Pharmaceutical Policy Reform*, 1 HEALTH AFFS. SCHOLAR 1, 2 (2023), https://academic.oup.com/healthaffairsscholar/article/1/1/qxad004/7203675 ("[T]hrough the negotiation process . . . the IRA effectively reduces the monopoly pricing that companies can expect to recoup many years after a drug has entered the market, although the IRA does not formally impact companies' exclusive rights."); *accord* GOLDMAN ET AL., *supra* note 67, at 8 fig. 1.

[69] *See* GOLDMAN ET AL., *supra* note 67, at 4 ("Lowered revenues [due to negotiation] may lead to less research, especially for follow-on drug innovation."); Suchita Shah et al., *Navigating the Inflation Reduction Act's Impact on Drug Pricing and Innovation*, BOSTON CONSULTING GRP. (2023), https://www.bcg.com/publications/2023/navigating-inflation-reduction-act-impact-on-drug-pricing-innovation ("[T]he IRA will reduce the return on R&D overall.").

[70] *See* PHILIPSON & DURIE, *supra* note 67, at 9 tbl.4 (estimating impacts of the Program on pharmaceutical revenue and R&D)).

[71] *See, e.g.*, Sachs et al., *supra* note 68, at 1 (arguing that the "IRA opponents' innovation concerns are overstated and oversimplified, overlooking important dimensions of innovation for patients.").

[72] *See* Jeannie Baumann, *Drug Negotiations Will Drive Biosimilars as Patent Tactics Shift*, BLOOMBERG LAW (Aug. 25, 2022), https://news.bloomberglaw.com/health-law-and-business/drug-negotiations-will-drive-biosimilars-as-patent-tactics-shift.

[73] *See* Richard Frank et al., *Biosimilar Competition: Early Learning*, 31 HEALTH ECON. 647 (2022).

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

[75] *See* Shah et al., *supra* note 69, at 6 ("Of course, it is important to keep in mind that the IRA is just one consideration among many when evaluating R&D decisions. Out-innovating and bringing to market medicines that are highly efficacious and differentiated will still be the ticket to success. Additionally, despite the further incentive shift toward biologics, small molecules often do have a greater ability to be used by underserved populations.").

[76] *See* Arti K. Rai et al., *Cryptic Patent Reform Through the Inflation Reduction Act* 20–21 (U. Mich. Law & Econ. Working Papers, Paper No. 256, 2023), https://repository.law.umich.edu/law_econ_current/256.

benefit analysis when a manufacturer decides whether to file a patent lawsuit seeking to prevent the entry of a generic or biosimilar competitor.[77]

Potential Effects of the Program on Drug Prices

The Congressional Budget Office (CBO) forecasts that the Program will reduce net prices for selected drugs by about 50%, on average, and that the Secretary will have sufficient leverage to negotiate some prices below the level of the MFP.[78] The CBO also expects Medicare drug prices to be affected by other IRA provisions besides the Program. For example, a separate IRA provision requires that manufacturers pay rebates to HHS if certain Part B- and D-covered drugs have price increases above an allowable rate of inflation. The mandatory rebate is separate from the Program, but includes drugs with an MFP.[79] The CBO expects that the mandatory rebate provision will slow drug price growth in Part D, even though manufacturers could attempt to set higher launch (list) prices for new drugs to offset some of its impact.

Overall, the CBO forecasts that under the IRA "the number of drugs that would be introduced to the U.S. market would be reduced by about 1 over the 2023-2032 period, about 5 over the subsequent decade, and about 7 over the decade after that."[80]

The federal government has also asserted that in some cases manufacturers could realize increased revenues if their products were selected for negotiation under the Program. For example, in a recent motion to dismiss filed by the government in a lawsuit challenging the constitutionality of the IRA, the government argued the pharmaceutical industry's claims of financial harm from the IRA were speculative, stating that "[c]ontrary to the tone of pessimistic inevitability in Plaintiffs' filings, it is possible that manufacturers will agree to prices that result in flat or even *greater* revenue for them…."[81] The government pointed to the IRA formula for determining a Part D drug's MFP, which is the lower of the Part D average net price or the nonfederal AMP. (See "Selected Drug Negotiation Provisions of the IRA.") If the Part D average net price turned out to be the lower price, the MFP ceiling would be the drug's Part D price minus any rebates and certain other price concessions that the manufacturer provided to the insurers that offer Part D plans. In other words, the government argued that the MFP could be near the manufacturer's current net price.[82]

Though not explicitly described in the legal filing, the IRA includes other provisions that could reduce the need for manufacturers to provide the same level of rebates for drugs with an MFP going forward. For example, manufacturers often provide rebates to Part D sponsors (insurers) and their pharmacy benefit managers to ensure that their drugs are included on Part D plan formularies or are placed on a lower-cost formulary tier. The IRA requires that Part D plans cover all drugs with a negotiated MFP, meaning manufacturers of those drugs might not need to provide

[77] *Id.*

[78] CBO, *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act* (Feb. 2023), https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf. CBO forecasts that the negotiation provisions will reduce federal drug spending under Medicare by $25 billion in 2031. Average Part D net prices will be 9% lower in 2031, and average Part B prices will be 8% lower.

[79] *Id.*

[80] CBO, SUMMARY ESTIMATED BUDGETARY EFFECTS OF PUBLIC LAW 117-169, at 15 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf. The CBO stated that "[t]he amounts in this estimate are in the middle of the distribution of possible outcomes, by CBO's assessment, and they are subject to uncertainty." *Id.*

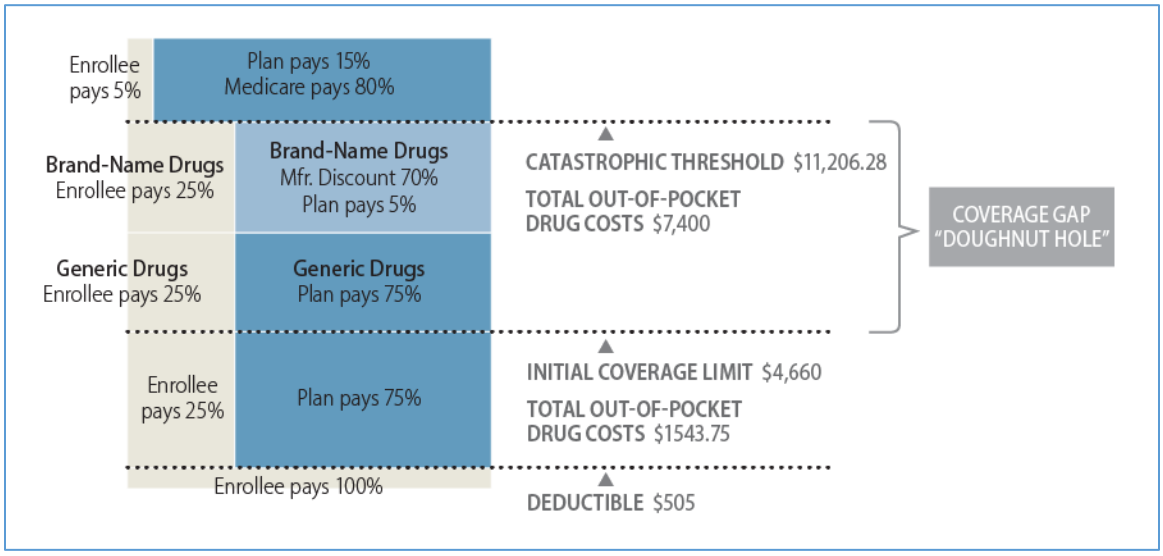
[81] Defendant's Motion to Dismiss at 8, Dayton Area Chamber of Com., et al. v. Becerra, No. 23-0156 (S.D. Ohio Aug. 11, 2023), ECF No. 33.

[82] *Id.*

rebates at the same level going forward.[83] Depending on the Secretary's decision on a final MFP for a drug at the end of the negotiation process, and negotiations with Part D plans regarding formulary placement, a manufacturer's net price after negotiation could be near the current net levels.[84]

The government added that being selected for a negotiated MFP for a drug "will also trigger other unequivocal benefits to its manufacturer," namely an exemption from the Part D Manufacturer Discount Program.[85] Under current law, manufacturers that participate in Part D must provide a 70% discount on brand-name biologic and biosimilar drugs purchased by enrollees with sufficient drug spending to reach a phase of the annual benefit known as the doughnut hole. (See **Figure 1**.) For 2023, enrollees enter the doughnut hole when they have $4,660 in total drug spending, and exit when they have about $11,000 in total drug spending ($7,400 in out-of-pocket spending). If an enrollee were prescribed a brand-name drug that cost $40,000 per year, for example, the manufacturer would provide a 70% discount only on the portion of the drug spending that was incurred in the doughnut hole.[86]

Figure 1. 2023 Medicare Part D Standard Benefit



Source: CRS visual based on CMS program information.

Note: CMS has not yet released the 2025 Part D deductible.

[83] CMS REVISED GUIDANCE, *supra* note 19. According to CMS, the statute requires Part D plans to include on their formularies all dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect. For the 2026 plan year, CMS is not requiring that plan sponsors put drugs with an MFP on lower-cost formulary tiers, but plans to use the Part D formulary review process to ensure plan sponsors do not discriminate against drugs with MFPs.

[84] *Id.* According to CMS, the statute requires Part D plans to include on their formularies all dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect. CMS is not requiring that plan sponsors put drugs with an MFP on lower-cost formulary tiers, but plans to use its formulary review process to ensure plan sponsors do not discriminate against drugs with MFPs.

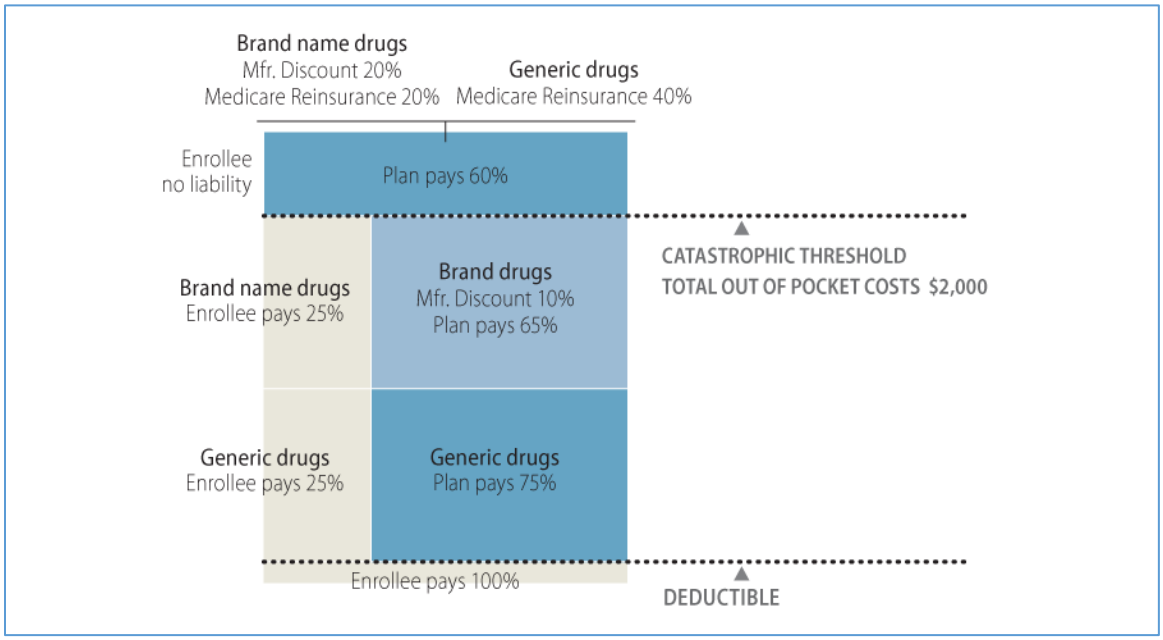
[85] Defendant's Motion to Dismiss at 10, Dayton Area Chamber of Com., et al. v. Becerra, No. 23-0156 (S.D. Ohio Aug. 11, 2023), ECF No. 33.

[86] CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*, coordinated by Katherine M. Kehres (2023).

The IRA eliminates the Part D doughnut hole in 2025. (See **Figure 2**.) Instead, drug manufacturers that participate in Part D will be required to provide a 10% discount on drugs purchased by enrollees between the annual deductible and $2,000 in out-of-pocket spending[87] and a 20% discount on drugs purchased by enrollees when they have more than $2,000 in out-of-pocket spending. Because the required discounts going forward would apply to the full price of a drug, some manufacturers could provide much higher discounts than under the current program.[88] According to CMS:

> So even if prices for a selected drug fall, any losses could be offset (or more) by exemption from the obligation to offer these discounts—especially if the "maximum fair price" comes in at or near the ceiling price. Indeed, depending on how all these variables shake out, a manufacturer of a selected drug could even see increased revenue.
>
> To be sure, it is possible that the "maximum fair price" for some selected drugs will be lower than the ceiling price—perhaps significantly so. After all, Congress directed CMS to "aim[] to achieve the lowest maximum fair price" that it can persuade manufacturers to accept.[89]

Figure 2. 2025 Medicare Part D Standard Benefit



Source: CRS visual based on CMS program information.

Note: CMS has not yet released the dollar amount of the 2025 Part D deductible or estimated total drug spending needed to accumulate $2,000 in out-of-pocket spending.

Industry and academic studies have posited varying outcomes for drug pricing under the IRA. Forecasts differ based on assumptions about the drugs to be selected for Program negotiation, and

[87] CMS has not released an estimate for the 2025 deductible for total drug spending needed to generate $2,000 in out-of-pocket spending.

[88] The MFP for a drug is to be adjusted annually to account for inflation, and Medicare beneficiaries may not be charged more than the adjusted MFP price.

[89] Defendant's Motion to Dismiss at 10, Dayton Area Chamber of Com., et al. v. Becerra, No. 23-0156 (S.D. Ohio Aug. 11, 2023), ECF No. 33.

manufacturer responses.[90] Lawmakers are debating legislation in the 118th Congress that would make further changes to Medicare and the commercial market, including regulation of pharmacy benefit managers and broader requirements for drug price transparency, that could also affect prescription drug pricing and distribution.

Author Information

Kevin J. Hickey
Legislative Attorney

Hannah-Alise Rogers
Legislative Attorney

Suzanne M. Kirchhoff
Analyst in Health Care Financing

Disclaimer

[90] *See, e.g.,* Benjamin Rome et al., *Simulated Medicare Drug Price Negotiation Under the Inflation Reduction Act of 2022*, JAMA HEALTH FORUM (Jan. 27, 2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2800864.