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SUMMARY

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Administrative Procedure Act (APA) Challenges to the Medicare Drug Price Negotiation Program

Congress created the Medicare Drug Price Negotiation Program (the Program) through the budget reconciliation measure known as the Inflation Reduction Act (IRA; P.L. 117-169), which became law on August 16, 2022. The Program allows Medicare to negotiate the prices of certain Medicare drugs directly with drug manufacturers for the first time. The Centers for Medicare and Medicaid Services (CMS), the division of the U.S. Department of Health and Human Services (HHS) tasked with administering the Program, has issued several guidance documents explaining the Program's initial implementation. On August 29, 2023, CMS selected the first 10 Medicare Part D drugs that will be subjected to negotiated prices beginning in 2026. The agency announced the negotiated prices for those drugs on August 14, 2024.

In summer 2023, several drug manufacturers and trade associations representing manufacturers challenged the law before federal district courts across the country. The plaintiffs made various arguments in different lawsuits, including that the law is unconstitutional under the First, Fifth, and Eighth Amendments. They also alleged violations of the Nondelegation Doctrine and the Spending Clause. In addition, a few manufacturers have challenged the guidance that CMS issued related to the Program's implementation under the Administrative Procedure Act (APA). Those lawsuits alleged that CMS exceeded its authority under the statute in the way that it defined certain terms, including a qualifying single source drug (QSSD), and other standards that the agency put in place, including the requirement that competitor generic drugs be subject to "bona fide" marketing.

Of the 10 cases initially filed, one was voluntarily dismissed, and eight have been decided at the federal district court level. So far, both the manufacturers' APA challenges and constitutional challenges have been unsuccessful. Specifically for the APA challenges, the district courts held that the drug manufacturers lacked Article III standing to bring the challenges, and that some of the challenges were barred by the IRA's preclusion of administrative and judicial review. As of the date of this writing, all of the district court decisions have been appealed, and most of the appeals are currently pending before the U.S. Courts of Appeals for the Second, Third, and Sixth Circuits. One decision dismissing a case on procedural grounds was appealed to the Fifth Circuit, which issued a decision remanding the case back to the district court for further proceedings.

This report explains the APA arguments brought by AstraZeneca Pharmaceuticals and Novo Nordisk, the government's responses to these claims, and the federal district courts' decisions in both cases. The constitutional claims are outside the scope of this report but are discussed in CRS Report R47682, *Constitutional Challenges to the Medicare Drug Price Negotiation Program*, by Hannah-Alise Rogers. The report concludes by identifying relevant considerations for the 118th Congress as the litigation proceeds.

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In 2022, Congress created the Medicare Drug Price Negotiation Program (the Program) through a budget reconciliation measure known as the Inflation Reduction Act (IRA).[1] The IRA authorizes the Secretary of the Department of Health and Human Services (HHS) to negotiate the prices of certain single-source drugs and biological products under Medicare Part B[2] (physician administered drugs) and Medicare Part D[3] (retail prescription drugs). The IRA directed the HHS Centers for Medicare and Medicaid Services (CMS) to implement the first three years of the Program (known as price years 2026-2028) through "program instruction or other forms of program guidance."[4] For the initial price years 2026 and 2027, only Medicare Part D drugs are eligible for selection; Part B drugs become eligible for selection in price year 2028.[5]

The IRA requires HHS to publish a list of selected drugs, enter into agreements with manufacturers of the drugs selected for negotiation, negotiate a maximum fair price (MFP) for those drugs with manufacturers, and monitor manufacturer compliance with Program requirements.[6] CMS selected the first 10 drugs for price negotiation on August 29, 2023, including AstraZeneca's drug Farxiga and Novo Nordisk's Fiasp and NovoLog products.[7] In August 2024, HHS announced the prices of the first 10 selected drugs, which take effect on January 1, 2026.[8] According to updated agency guidance, the agency plans to select an additional 15 drugs for negotiation in February 2025; those prices will take effect on January 1, 2027.[9]

Beginning in June 2023, several pharmaceutical manufacturers, including AstraZeneca and Novo Nordisk, as well as pharmaceutical trade associations, sued CMS in various federal district courts across the country. At least 10 lawsuits have challenged the constitutionality of the Program on various grounds, including under the First, Fifth, and Eighth Amendments.[10] In addition to these and other constitutional arguments, AstraZeneca and Novo Nordisk claimed that CMS's implementation of the Program violates the Administrative Procedure Act (APA).

This Report explains AstraZeneca and Novo Nordisk's APA claims and the district courts' decisions on those claims. In both cases, the pharmaceutical companies and the government filed cross motions for summary judgment. In AstraZeneca's case, the federal district court in

[1] For more information on various health provisions of the IRA, *see* CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*, coordinated by Katherine M. Kehres (2023).

[2] For more information about Medicare Part B, *see* CRS Report R40425, *Medicare Primer*, coordinated by Patricia A. Davis (2020).

[3] For more information about Medicare Part D, *see* CRS Report R40611, *Medicare Part D Prescription Drug Benefit*, by Laura A. Wreschnig (2023).

[4] 42 U.S.C. § 1320f-1 note.

[5] *Id.* § 1320f-1(a)(3). For more information about how CMS selected the first 10 drugs, see CRS Report R47555, *Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations*, by Hannah-Alise Rogers (2023).

[6] 42 U.S.C. § 1320(a).

[7] Press Release, HHS, HHS Selects the First Drugs for Medicare Drug Price Negotiation (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.

[8] Press Release, CMS, Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026 (Aug. 15, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026.

[9] Memorandum from Meena Seshamani, Deputy Administrator and Director of the Center for Medicare, on Medicare Drug Price Negotiation to Interested Parties 26 (Oct. 2, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf [hereinafter Guidance for Price Year 2027].

[10] For more information on the constitutional challenges, *see* CRS Report R47682, *Constitutional Challenges to the Medicare Drug Price Negotiation Program*, by Hannah-Alise Rogers, at 3 (2024).

Delaware issued its decision on March 1, 2024.[11] The federal district court in New Jersey issued its decision in Novo Nordisk's case on July 31, 2024.[12] Both rulings have been appealed to the U.S. Court of Appeals for the Third Circuit.[13]

Legal Background

The Administrative Procedure Act

The APA is a federal statute that permits judicial review of "agency action[s] made reviewable by statute," as well as "final agency action for which there is no other adequate remedy in a court."[14] The APA directs reviewing courts to "hold unlawful and set aside agency action, findings, and conclusions" when they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[15] Additionally, agency actions that are characterized as "ultra vires" may also be reviewed under the APA.[16] In an ultra vires action, even a statute that precludes judicial review of an agency's determinations may be reviewed by a court if the agency's action can be characterized as violating an unambiguous statutory mandate.[17]

Defining a Qualifying Single Source Drug

Before selecting the first 10 drugs for negotiation, the Secretary of HHS identified the pool of "qualifying single source drugs"[18] (QSSDs) in accordance with the framework set forth in the IRA. For price year 2026, for a small molecule drug to be a QSSD,[19] it had to be a Medicare Part D drug that (1) was approved by the U.S. Food and Drug Administration (FDA) and marketed pursuant to such approval, (2) had been FDA approved for at least seven years, and (3) did not have an approved and marketed generic version.[20] For a *biologic* to be a QSSD,[21] the product had to be a Medicare Part D drug that (1) was licensed under the Public Health Service Act (PHSA) and was marketed under the license, (2) had been licensed for at least 11 years, and (3) did not have a licensed and marketed *biosimilar*.[22]

[11] AstraZeneca Pharms. v. Becerra, No. 23-931, 2024 WL 895036 (D. Del. Mar. 1, 2024).

[12] Novo Nordisk v. Becerra, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024).

[13] Notice, AstraZeneca Pharms. v. Becerra, No. 24-1819 (3d Cir. May 2, 2024), ECF No. 1; Notice, Novo Nordisk v. Becerra, No. 24-2510 (3d Cir. Aug. 19, 2024), ECF No. 1.

[14] 5 U.S.C. §§ 551–559; CRS Legal Sidebar LSB10558, *Judicial Review Under the Administrative Procedure Act (APA)*, by Jonathan M. Gaffney.

[15] 5 U.S.C. § 706(2)(A). For more information on judicial review under the APA, *see* CRS Report R44699, *An Introduction to Judicial Review of Federal Agency Action*, by Jared P. Cole, at 9 (2016).

[16] CRS Report R44699, *supra* note 15, at 5.

[17] *See, e.g.*, Key Medical Supply, Inc. v. Burwell, 764 F.3d 955, 962 (8th Cir. 2014).

[18] 42 U.S.C. § 1320f-1(e).

[19] A small molecule drug is one that is synthesized in a laboratory. For more information, see CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*, by Amanda K. Sarata and Hassan Z. Sheikh.

[20] 42 U.S.C. § 1320f-1(e).

[21] The Public Health Service Act defines a "biological product" (or *biologic*) as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i)(1).

[22] *Id.* § 1320f-1(e).

After identifying the QSSDs, CMS calculated Medicare's total Part D expenditures for each QSSD by looking at Part D prescription drug cost and payment (PDE) data between June 1, 2022, and May 31, 2023.[23] The 50 drugs with the highest expenditures were considered "negotiation-eligible drugs."[24] In determining if a QSSD meets the definition of a negotiation-eligible drug, the IRA directed CMS to "use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug . . . and not based on the specific formulation or package size of the drug."[25] After applying any relevant statutory exceptions, CMS then selected the top 10 highest-spend Medicare drugs for negotiation.[26]

In its Initial Guidance issued in March 2023, CMS stated it would apply the data aggregation provision discussed above to the definition of what it considered a single QSSD.[27] CMS announced that "all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA)," even if the products are marketed under different NDAs, would be treated as one drug for QSSD determinations.[28] Similarly, CMS said that all dosage forms and strengths of a biologic "with the same active ingredient and the same holder of a Biologics License Application (BLA),"[29] even if the products are marketed under different BLAs, would be considered the same QSSD. CMS received a variety of stakeholder comments in response to this Initial Guidance, which it addressed in the Revised Guidance issued in June 2023.[30] In that guidance, CMS defended its decision to define QSSD so that multiple products with the same active ingredient could be selected as a single QSSD, stating that "the aggregation rules under [the IRA] are clear."[31] While some commenters suggested that a QSSD should be defined based on each distinct NDA or BLA, CMS responded that such an approach would be "inconsistent" with the statute.[32]

Similarly, in Guidance for Price Year 2027, released in October 2024, the agency again addressed comments on the aggregation of various dosage forms and strengths of drugs with the same active moiety for purposes of identifying the QSSD, defending its position in previous guidance.[33] CMS agreed with comments arguing that aggregating across dosage forms and strengths would "decrease incentives for pharmaceutical manufacturers to engage in product hopping."[34] The

[23] Memorandum from Meena Seshamani, Deputy Administrator and Director of the Center for Medicare, on Medicare Drug Price Negotiation to Interested Parties, at 12 (Mar. 15, 2023), https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf [hereinafter Initial Guidance].

For more information about PDE data, *see* Centers for Medicare & Medicaid Servs., Questions and Answers on Obtaining Prescription Drug Event (PDE) Data, https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/downloads/partdclaimsdataqa.pdf (last visited Nov. 13, 2024).

[24] Initial Guidance, *supra* note 23, at 15.

[25] 42 U.S.C. § 1320f-1(d)(3)(B).

[26] CRS Report R47555, *Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations*, by Hannah-Alise Rogers, at 3 (2023).

[27] Initial Guidance, *supra* note 23, at 8.

[28] *Id.* In order to market a new drug in the United States, a manufacturer must file and FDA must approve an NDA. *See generally* 21 U.S.C § 355. For more information, see CRS In Focus IF11083, *supra* note 19.

[29] *Id.* In order to market a biologic in the United States, a manufacturer must file and FDA must approve a BLA. *See generally* 42 U.S.C. § 262; *see also* CRS In Focus IF11083, *supra* note 19.

[30] Memorandum from Meena Seshamani, Deputy Administrator and Director of the Center for Medicare, on Medicare Drug Price Negotiation to Interested Parties, at 11 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf [hereinafter Revised Guidance].

[31] *Id.*

[32] *Id.*

[33] Guidance for Price Year 2027, *supra* note 9, at 12.

[34] *Id.*

agency reiterated its position that the statute's requirements "ensure[] that products by the same sponsor with the same active moiety / active ingredient are subject to the same processes," which limits manufacturers' ability to "inappropriately exclude from the Negotiation Program drug products that might otherwise be eligible based on modest or minor modifications."[35]

Bona Fide Marketing of a Product

As described above, the IRA's definition of QSSD is limited to small molecule drugs and biologics with no generic or biosimilar versions on the market. Thus, if a product has approved and marketed generic or biosimilar competition, it will not qualify as a QSSD for purposes of selection for price negotiation. In its Initial Guidance, CMS stated that it will consider a competing generic drug or biosimilar to be marketed "when the[] data reveal that the manufacturer . . . has engaged in bona fide marketing of that drug or product."[36] CMS advised that the agency "intends to monitor whether robust and meaningful competition exists in the market."[37] In responding to stakeholder comments about the "bona fide marketing" requirement, CMS noted in its Revised Guidance that "Congress contemplated that a generic or biosimilar must have a continuing presence on the market in order to affect CMS's determination whether a drug should be selected" as a QSSD.[38]

In response to critiques that the agency lacked the authority to create the "bona fide marketing" requirement, CMS stated in its Guidance for Price Year 2027 that Congress "purposefully used different terminology" in the IRA to require a generic or biosimilar product to have a "continuing presence on the market in order to affect" the QSSD status.[39] The agency pointed to the IRA's use of the phrase "is marketed," contrasting it with a different section of the Social Security Act which refers to the date that a drug is "first marketed."[40] The agency pressed that the statute "requires more than solely token or *de minimis* availability of the [competing] products," to disincentivize manufacturers from executing a market-limiting agreement that could result in decreased product availability.[41] CMS also described the "time lag" in PDE data (i.e., the time difference between when a generic or biosimilar competitor first enters the market and when it is actually used to fill Part D prescriptions) as "relatively short," arguing that Part D plans are required to submit updated data to CMS within 30 days of receipt of the claim.[42]

The IRA's Limitations on Judicial Review

The IRA limits administrative and judicial review of some of CMS's determinations for purposes of carrying out the Program. First, the statute precludes judicial review of the determination of drug units, which it defines as the "lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished."[43] Second, the IRA precludes review of certain aspects of the determination of whether the drug is a QSSD (under Section 1320f-1(e)), whether it is a negotiation-eligible drug (under

[35] *Id.* at 13.

[36] Initial Guidance, *supra* note 23, at 10.

[37] *Id.* at 67.

[38] Revised Guidance, *supra* note 30, at 72.

[39] Guidance for Price Year 2027, *supra* note 9, at 20.

[40] *Id.*

[41] *Id.*

[42] *Id.* at 21.

[43] 42 U.S.C. §§ 1320f(c)(6), 1320f-7; *see also* Guidance for Price Year 2027, *supra* note 9.

Section 1320f-1(d)), and the selection of drugs (under Section 1320f-1(b)).[44] Third, review of the "determination" of the MFP (under Sections 1320f-3(b) and (f)) is also barred.[45] Finally, the IRA precludes review of the agency's determination of renegotiation-eligible drugs (under Section 1320f-3(f)(2)-(3)), which includes CMS's decision to reselect a drug for negotiation in subsequent years and renegotiate its MFP.[46]

While these limitations on judicial review do not stop manufacturers from challenging the underlying constitutionality of the IRA, as discussed below, at least one court has interpreted them as barring certain other APA claims.[47] If additional cases challenging CMS's implementation of the Program are filed under the APA in the future, courts may have to decide whether the IRA's preclusion language limits federal courts' subject matter jurisdiction over those claims.[48]

Drug Manufacturers' Motions for Summary Judgment

Drug manufacturers AstraZeneca and Novo Nordisk each brought challenges against CMS's implementation of the Program under the APA. AstraZeneca brought its case in federal district court in Delaware; Novo Nordisk brought its challenge in federal district court in New Jersey. For price year 2026, CMS selected AstraZeneca's drug Farxiga, which is used to treat diabetes.[49] The agency also selected Novo Nordisk's Fiasp and NovoLog products, all of which use the same active ingredient, insulin aspart; these products are also used to treat diabetes.[50] The nature of the manufacturers' APA claims differs from the other constitutional challenges brought against the Program. The constitutional claims address Congress' underlying authority to enact the IRA,[51]

[44] 42 U.S.C. § 1320f-7(2). Section 1320f-1(b) authorizes the Secretary to rank negotiation-eligible drugs and, for price year 2026, select the 10 drugs with the highest total Medicare expenditures. *Id.* § 1320f-1(b)(1). Section 1320f-1(d) defines "negotiation-eligible drug," as well as "Part D High Spend Drugs" and "Part B High Spend drugs," for purposes of the Program. *Id.* § 1320f-1(d)(1)(A)-(B). Section 1320f-1(d)(2) also contains the small biotech exception, outlining which Part B and D drugs qualify for the exception. *See generally id.* § 1320f-1(d)(2)(A)-(B). The definition of QSSD is contained in Section 1320f-1(e)(1), authorized generics are defined in Section 1320f-1(e)(2), and the exceptions for orphan drugs, low-spend drugs, and plasma-derived products are contained in Section 1320f-1(e)(3). *See generally id.* § 1320f-1(e)(1)-(3).

[45] 42 U.S.C. § 1320f-7(3). Section 1320f-3(b)(1) authorizes the Secretary to develop and use a methodology to "achieve" the MFP. *Id.* § 1320f-3(b)(1). Several provisions within Section 1320f-3(b)(2) provide specific timelines for CMS to implement the Program, including dates for drug manufacturers to submit information to CMS, for CMS to make an initial offer, for manufacturers to make a counteroffer, and for CMS to respond. *Id.* § 1320f-3(b)(2)(A)-(E). This subsection also prohibits the Secretary from both making an offer that exceeds the ceiling price, as described in § 1320f-3(c), and from offering a price below the floor described in § 1320f-3(d), if applicable. *Id.* § 1320f-3(b)(2)(F)(i)-(ii).

[46] *Id.* § 1320f-7(4). Section 1320f-3(f) describes the renegotiation process, to begin in 2028, for negotiation-eligible drugs. *Id.* § 1320f-3(f). CMS has not yet issued guidance for the renegotiation process of drugs. *See* Guidance for Price Year 2027, *supra* note 9, at 44.

[47] *See, e.g.*, Novo Nordisk Inc. v. Becerra, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024).

[48] For more information about the potential interpretations of the limitations on judicial review, *see* CRS Report R47555, *Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations*, by Hannah-Alise Rogers (2023).

[49] Press Release, HHS, HHS Selects the First Drugs for Medicare Drug Price Negotiation (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.

[50] *Id.*

[51] For more information on the constitutional challenges, see CRS Report R47682, *supra* note 10.

while the APA claims address CMS's interpretation of the statute and how the agency has operationalized the program.[52]

AstraZeneca's Arguments

Both AstraZeneca and Novo Nordisk challenged CMS's definition of QSSD and the bona fide marketing requirement under the APA. In its motion for summary judgment, AstraZeneca argued that CMS's QSSD definition and the bona fide marketing requirement violate the plain language of the IRA and are arbitrary and capricious under the APA.[53] The drugmaker claimed that multiple drug products can be the same QSSD "*only* where the . . . products were approved by the FDA under the same NDA or BLA" and that CMS "lacks the authority to aggregate different drug products approved under different NDAs or BLAs" as the same QSSD.[54] AstraZeneca argued that QSSDs should be based on distinct NDAs or BLAs, not on active ingredients, because the IRA definition of QSSD cross-references a term defined in the Medicare statute, which, in turn, cross-references a term defined in the Medicaid statute that ultimately refers to distinct NDAs or BLAs.[55] The company further alleged that the effects of CMS's QSSD policy "[would] be felt across AstraZeneca's product portfolio" because the existing definition could subject a new Farxiga product to immediate price negotiation if the product contains the same active ingredient as the original product.[56] AstraZeneca also said that the QSSD definition is arbitrary and capricious because it "discourages" manufacturers from improving their existing products.[57]

With respect to the bona fide marketing requirement, AstraZeneca claimed that CMS's interpretation is contrary to the plain language of the IRA as well as arbitrary and capricious.[58] The manufacturer argued that "[n]owhere in the law did Congress include qualifying language that might narrow or otherwise change the ordinary meaning of the word 'marketed.'"[59] AstraZeneca described the IRA's marketing requirement as a "check-the-box inquiry," and pointed to an existing Medicaid Drug Rebate Program policy that defines "marketed" by reference to when a product is available for sale.[60] The company also argued that in *Asgrow Seed Co. v. Winterboer*,[61] the Supreme Court found that the term "marketing" usually "refers to the act of holding forth property for sale."[62] AstraZeneca claimed that CMS's "holistic" and "totality of the circumstances" inquiry is too subjective and, as a result of CMS's bona fide marketing

[52] *See generally* Opening Brief in Support of Plaintiffs' Motion for Summary Judgment, AstraZeneca Pharms. LP v. Becerra, No. 23-931 (D. Del. Sept. 26, 2023), ECF No. 19; Plaintiffs' Memorandum in Support of Their Motion for Summary Judgment, Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814, (D.N.J. Dec. 8, 2023), ECF No. 28.

[53] Opening Brief in Support of Plaintiffs' Motion for Summary Judgment at 14, AstraZeneca Pharms. LP v. Becerra, No. 23-931 (D. Del. Sept. 26, 2023), ECF No. 19.

[54] *Id.*

[55] *Id.* at 15. The IRA references the definition of a "covered Part D drug" in the Medicare statute (42 U.S.C. § 1395w-102(e)). That section of the Medicare statute references the definition of "covered outpatient drug" in the Medicaid statute (42 U.S.C. § 1496r-8(k)(2)(A)-(B)), which references the drug's NDA or BLA.

[56] Opening Brief in Support of Plaintiffs' Motion for Summary Judgment at 16–17, AstraZeneca Pharms. LP v. Becerra, No. 23-931, (D. Del. Dec. 8, 2023), ECF No. 19.

[57] *Id.* at 3.

[58] *Id.* at 18.

[59] *Id.* at 19.

[60] *Id.*

[61] 513 U.S. 179 (1995).

[62] *Id.* at 187.

requirement, a product's price could be subject to negotiation while also being subject to generic competition.[63]

Novo Nordisk's Arguments

Novo Nordisk took a slightly different approach in its summary judgment motion, claiming that CMS exceeded its statutory authority in several ways, including by selecting more than 10 drugs for negotiation, selecting a biologic that had not been marketed for at least 11 years, and by selecting QSSDs that have generic or biosimilar competition.[64] The drugmaker argued that by selecting six of its NovoLog and Fiasp products as a single QSSD, CMS violated the IRA's requirement that CMS select no more than 10 drugs for price year 2026.[65] Similar to AstraZeneca, Novo Nordisk said that QSSDs should be based on each NDA or BLA, because FDA approvals and exclusivities are product specific, noting that the IRA "says nothing about active moieties or active ingredients."[66]

The company also argued that CMS's focus on the active moiety (i.e., insulin aspart), rather than a specific product, has led to the selection of both Part B and Part D drugs, in violation of the IRA, which provides that only Part D drugs may be selected for negotiation in 2026.[67] The manufacturer pointed out that some of its Fiasp products are covered primarily under Part D, while others are covered primarily under Part B, but that CMS has included both types of products on the list of selected drugs.[68] Novo Nordisk also argued that the IRA's provision limiting administrative and judicial review should not apply, alleging that CMS's action is ultra vires under the APA (i.e., beyond its legal authority).[69]

Government's Cross Motions for Summary Judgment

The government opposed the drug manufacturers' motions and filed cross motions for summary judgment in both cases, making both procedural and substantive arguments. The government first asserted that AstraZeneca lacked standing to bring the APA challenges, because the company did not demonstrate that the QSSD definition impacted Farxiga's selection.[70] According to the government, Farxiga is manufactured under a single NDA and has one dosage form, two strengths, and no currently approved generic competitors.[71] Thus, the government said,

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[63] Opening Brief in Support of Plaintiffs' Motion for Summary Judgment at 21, AstraZeneca Pharms. LP v. Becerra, No. 23-931 (D. Del. Sept. 26, 2023) ECF No. 19.

[64] Plaintiffs' Memorandum in Support of Their Motion for Summary Judgment, Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814 (D.N.J. Dec. 8, 2023), ECF No. 28.

[65] *Id.* at 17; *see* 42 U.S.C. § 1320f-1(a).

[66] Plaintiffs' Memorandum in Support of Their Motion for Summary Judgment at 19, Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814 (D.N.J. Dec. 8, 2023), ECF No. 28.

[67] 42 U.S.C. § 1320f-1(d).

[68] Plaintiffs' Memorandum in Support of Their Motion for Summary Judgment at 23, Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814 (D.N.J. Dec. 8, 2023), ECF No. 28.

[69] 42 U.S.C. § 1320f-7. *See* CRS Report R47555, *Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations*, by Hannah-Alise Rogers, at 10 (2023); CRS Report R44699, *An Introduction to Judicial Review of Federal Agency Action*, by Jared P. Cole, at 5 (2016).

[70] Defendants' Opposition to Plaintiffs' Motion for Summary Judgment and Cross-motion at 14, AstraZeneca Pharms. LP v. Becerra, No. 23-931, 2024 WL (D. Del. Nov. 1, 2023), ECF No. 21.

[71] *Id.* at 15–16.

AstraZeneca was not actually harmed by CMS's interpretation of the QSSD definition and lacked standing to challenge it.[72]

The government next argued that the plain text of the IRA precludes judicial review of both AstraZeneca's and Novo Nordisk's claims, including their ultra vires challenges.[73] The government relied on several D.C. Circuit cases upholding provisions limiting judicial review in other parts of the Medicare statute, arguing that Congress's express preclusion of judicial review in the IRA makes the QSSD definition and the selection of drugs unreviewable.[74] The government pointed to *DCH Regional Medical Center v. Azar*, where a hospital challenged a Medicare payment amount, but where the Medicare Act limited judicial review of "any estimate" the Secretary used to calculate the payment.[75] The D.C. Circuit upheld a district court's dismissal of the case, finding that judicial review was precluded because the methodology HHS used to calculate the payment amount was "inextricably intertwined" with the estimate itself.[76] Even though the hospital argued that the action was reviewable under the APA as ultra vires, the court disagreed, holding that CMS's payment methodology was not an "obvious violation of a clear statutory command."[77] As in the *DHC Regional Medical Center* case, the government similarly argued in its summary judgment motions against AstraZeneca and Novo Nordisk that because the statute precludes judicial review of the selection of drugs, the manufacturers' challenges to CMS's authority to "prescribe methodologies" for purposes of selection are "inextricably intertwined" with the selection itself and thus should fail.[78]

On the merits, the government argued in both cases that using active moieties and ingredients in the QSSD definition does not violate the IRA.[79] In the government's view, a drug's particular NDA is irrelevant because the statute clearly states that CMS should use "aggregated data across multiple dosage forms and strengths" and directs CMS to apply the negotiated price across different forms and strengths of the drug.[80] The government characterized the manufacturers' interpretation of the data aggregation provision as "nonsensical" and asserted that the Revised Guidance is not arbitrary or capricious because CMS reasonably explained its approach to the

[72] *Id.* at 17.

[73] *Id.* at 14; Memorandum of Law in Opposition to Plaintiff's Motion for Summary Judgment and in Support of Defendants' Cross-motion at 13, Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814 (D.N.J. Jan. 26, 2024), ECF No. 37.

[74] *E.g.*, Memorandum of Law in Opposition to Plaintiff's Motion for Summary Judgment and in Support of Defendants' Cross-motion at 14, Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814 (D.N.J. Jan. 26, 2024), ECF No. 37.

[75] *Id.* (citing DCH Reg'l Med. Ctr. v. Azar, 925 F.3d 503 (D.D.C. 2019)). The *DHC Regional Medical Center* case specifically concerned the calculation of disproportionate share hospital (DSH) payments under the Medicare statute. As the D.C. Circuit explained, the issue in the case was whether HHS's interpretation of the statute's "additional payment" for DSH hospitals was precluded from judicial review. 925 F.3d at 504. The statute lists three factors that the Secretary is to consider in the calculation of the DSH payment, and the statute says that "[t]here shall be no administrative or judicial review . . . [of] [a]ny estimate of the Secretary for purposes of determining the factors" described in the statute. 42 U.S.C. § 1395ww(r)(3)(A). The hospital challenging its DSH payment argued that judicial review was not precluded because it was challenging the *methodology* employed by the Secretary in the calculation of one of the factors, not the factor itself. *DCH Reg'l Med. Ctr.*, 925 F.3d at 505 (emphasis added). In finding that the statute precluded judicial review, the D.C. Circuit concluded, "In this statutory scheme, a challenge to the methodology for estimating uncompensated care is unavoidably a challenge to the estimates themselves. The statute draws no distinction between the two." *Id.* at 506.

[76] *DCH Reg'l Med. Ctr.*, 925 F.3d 503, 510.

[77] *Id.*

[78] Memorandum of Law in Opposition to Plaintiff's Motion for Summary Judgment and in Support of Defendants' Cross-motion at 18, Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814 (D.N.J. Jan. 26, 2024), ECF No. 37.

[79] *Id.* at 21; Defendants' Opposition to Plaintiffs' Motion for Summary Judgment and Cross-motion at 27, AstraZeneca Pharms. LP v. Becerra, No. 23-931 (D. Del. Nov. 1, 2023), ECF No. 21.

[80] 42 U.S.C. § 1320f-1(d)(3)(B).

QSSD definition.[81] The government claimed that an NDA-based approach would violate the statute, because different dosage forms and strengths of a drug can be approved under multiple NDAs, depending on how the manufacturer applied for FDA approval.[82] The government pointed to the statute's "repeated references to the possibility that a single negotiation-eligible drug would comprise multiple dosage forms, strengths, and formulations—and have multiple FDA approvals" and argued that these references "would make no sense if Congress had intended CMS to follow FDA's product-specific approach."[83] The government further reasoned that the QSSD definition ensures that drug manufacturers will not engage in "product hopping" as a way of avoiding negotiation, and that there is nothing arbitrary about a newly marketed product being subject to price negotiation.[84]

With respect to Novo Nordisk's argument that the QSSD conflates Part B and Part D drugs in violation of the statute, the government said the statute "directs CMS to select drugs based on relative *spending*—and makes only Medicare Part D spending a relevant ranking criterion for price applicability years 2026 and 2027."[85] In other words, the government says it is "immaterial" that the manufacturer's insulin drugs are reimbursed under both Parts B and D, because the "practical effect" of the statute is that Part B drugs are not selected for negotiation in price year 2026 unless they also have the highest Part D expenditures.[86] The government argued NovoLog meets both criteria and thus that the drug is not exempted from selection simply because it also receives reimbursement under Part B.[87]

Lastly, the government argued that CMS's bona fide marketing standard is consistent with the IRA.[88] The government explained that the standard is needed to ensure that manufacturers cannot avoid negotiation by contracting with a generic competitor to launch a *de minimis* amount of a generic drug or biosimilar, thereby exempting it from the QSSD definition.[89] The government also argued that the specific language of the IRA indicates that Congress intended for CMS to "exercise some judgment in applying the standard," and that the manufacturers' interpretation of the IRA would render the marketing requirement "meaningless."[90] The government disputed the relevance of other CMS interpretations of "marketing" that the manufacturers assert lack a bona fide requirement, arguing that in those instances de minimis marketing was not a concern.[91]

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[81] Defendants' Opposition to Plaintiffs' Motion for Summary Judgment and Cross-motion at 30, AstraZeneca Pharms. LP v. Becerra, No. 23-931 (D. Del. Nov. 1, 2023), ECF No. 21; Memorandum of Law in Opposition to Plaintiff's Motion for Summary Judgment and in Support of Defendants' Cross-motion at 27, Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814, 2024 WL 3594413 (D.N.J. Jan. 26, 2024), ECF No. 37; *see also* Revised Guidance at 11.

[82] 42 U.S.C. § 1320f-1(d)(3)(B).

[83] Memorandum of Law in Opposition to Plaintiff's Motion for Summary Judgment and in Support of Defendants' Cross-motion at 23, Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814 (D.N.J. Jan. 26, 2024), ECF No. 37.

[84] *Id.* at 27; Defendants' Opposition to Plaintiffs' Motion for Summary Judgment and Cross-motion at 31, AstraZeneca Pharms. LP v. Becerra, No. 23-931 (D. Del. Nov. 1, 2023), ECF No. 21. For more information about product hopping, see CRS In Focus IF11561, *Pharmaceutical Patenting Practices: A Legal Overview*, coordinated by Kevin J. Hickey (2020).

[85] Memorandum of Law in Opposition to Plaintiff's Motion for Summary Judgment and in Support of Defendants' Cross-motion at 27, Novo Nordisk, Inc. v. Becerra, No. 23-20814 (D.N.J. Jan. 26, 2024), ECF No. 37.

[86] *Id.* at 28.

[87] *Id.*

[88] Defendants' Opposition to Plaintiffs' Motion for Summary Judgment and Cross-motion at 32, AstraZeneca Pharms. LP v. Becerra, No. 23-931 (D. Del. Nov. 1, 2023), ECF No. 21.

[89] *Id.* at 33.

[90] *Id.* at 34, 36. *See* 42 U.S.C. § 1320f-1(c)(1)(B).

[91] Defendants' Opposition to Plaintiffs' Motion for Summary Judgment and Cross-motion at 38, AstraZeneca Pharms. LP v. Becerra, No. 23-931 (D. Del. Nov. 1, 2023), ECF No. 21.

District Court Decisions

AstraZeneca Pharms. v. Becerra

The federal district court in Delaware issued its decision on the cross motions for summary judgment in AstraZeneca's case on March 1, 2024, finding that the court lacked jurisdiction to consider the company's APA claims because the company lacked Article III standing.[92] Under Article III of the Constitution, federal court jurisdiction is limited to "Cases" and "Controversies," and a plaintiff must demonstrate standing in order to bring a lawsuit.[93] The Supreme Court has held that judicial standing is satisfied when the plaintiff demonstrates a "concrete, particularized, and actual or imminent" injury which was "likely caused by the defendant" and that "would likely be redressed by" a court.[94] In AstraZeneca's case, the company made several arguments to try to establish that it had standing, each of which the court found insufficient.

The court observed that AstraZeneca's arguments about the harm it suffered as a result of CMS's guidance wasn't the actual selection of its drug, which the court said "made sense," because neither the QSSD nor the bona fide marketing arguments "had any bearing on CMS's decision to designate Farxiga as a selected drug."[95] (In other words, even assuming AstraZeneca was correct that CMS's guidance on these two aspects of the Program was in excess of its statutory authority, that would not have led to a different outcome for AstraZeneca, because Farxiga would still have been selected for negotiation.) Instead, the company described the harm it suffered from CMS's guidance as a decrease in incentives to invest in further research and development, both for Farxiga and for other products.[96] The court was unpersuaded by these arguments, characterizing them as an "unprecedented theory" of standing, because the injuries were not concrete, actual, or imminent.[97] The court said, "Astrazeneca's alleged injury is premised on a hypothetical scenario that could only be realized *if* [the company] were to develop a new formulation or use of Farxiga's active moiety, *if* the FDA approved that new formulation or use under a new NDA, and *if* Farxiga were still a selected drug for the Program at that (unknown) time."[98] The necessity of the word "if", the court reasoned, demonstrates that the company had not suffered actual or imminent harm from the CMS guidance.[99] And with respect to the decrease in incentives to research and develop new drugs, the court said this argument did not establish standing because the "harm alleged . . . is too vague to establish a cognizable injury."[100]

As for AstraZeneca's other standing arguments, the court was likewise unpersuaded that the company had suffered an actual harm. The court found that AstraZeneca's arguments related to the bona fide marketing standard similarly failed and that the company's characterization of the alleged harm contained "many flaws."[101] The company argued that CMS's bona fide marketing

[92] AstraZeneca Pharms. LP v. Becerra, No. 23-931, 2024 WL 895036 at *13 (D. Del. Mar. 1, 2024), *appeal filed* No. 24-1819 (3d Cir. May 2, 2024).

[93] *Id.* at *7 (citing Lujan v. Defs. of Wildlife, 504 U.S. 559 (1992)).

[94] *Id.* (quoting TransUnion LLC v. Ramirez, 594 U.S. 413, 423 (2021)).

[95] *Id.*

[96] *Id.* at *8.

[97] *Id.*

[98] *Id.*

[99] *Id.*

[100] *Id.* at *11.

[101] *Id.* at *10.

requirement would harm its business by subjecting Farxiga to both generic competition and an MFP, but the court observed that the IRA does not "suggest[] in any way that a selected drug is not subject to the Act's price controls if it faces generic competition."[102] Rather, Section 1320f-1(c) of the IRA provides that a selected drug "shall not be subject to the negotiation process" if a generic is approved and marketed "before or during the negotiation period."[103] The court reasoned that because the price year 2026 negotiation period went from October 1, 2023, to August 1, 2024, and because Farxiga did not face generic competition during that time, the statute, rather than the agency's guidance, was the root of the issue.[104] The court thus held that the alleged harm from the agency's bona fide marketing test "cannot meet the causation and redressability requirements for standing, as it was not caused by the Guidance and could not be remedied by vacating the Guidance."[105] The court also said, among other reasons, that the company had not alleged or established that its selected drug would experience insufficient generic competition, and that it was "highly unlikely" that the 17 manufacturers who asked for FDA approval to market the generic of Farxiga thus far intended to do so "in only a de minimis manner."[106]

Finally, the court addressed the standing arguments that AstraZeneca raised during oral argument, but which it did not mention in its briefs.[107] At that time, the company stated that it was unable to accurately evaluate Farxiga's value for purposes of making a counteroffer to CMS, due to the agency's construction of the QSSD and the bona fide marketing requirements in the guidance.[108] The court disagreed, stating, "Of course, AstraZeneca *does* 'know the impact of CMS's [allegedly] flawed guidance on [its] ability to negotiate,'" because they described it "in detail" in the complaint and briefs.[109] The court thus found that the company could not "credibly argue that it is unable to understand the Guidance or how [it] applies as written to Farxiga."[110] The court also held that the company's argument was insufficient to support Article III standing, reasoning that "[t]he only uncertainty relating to the Guidance comes from the filing of this lawsuit."[111] Because the court found that AstraZeneca did not have Article III standing to bring any of its claims, it did not evaluate whether any of these claims were precluded by the statute's prohibition on judicial review.[112] AstraZeneca has appealed the district court's ruling to the U.S. Court of Appeals for the Third Circuit.[113]

Novo Nordisk v. Becerra

The New Jersey federal district court issued its decision on the cross motions filed in Novo Nordisk's case on July 31, 2024, finding that the manufacturer lacked both subject matter jurisdiction and standing to bring its APA challenges.[114] With respect to the drug manufacturer's

[102] *Id.*

[103] *Id.* (quoting 42 U.S.C. § 1320f-1(c)(2)).

[104] *Id.* at *10.

[105] *Id.*

[106] *Id.* at *11.

[107] *Id.* at *12.

[108] *Id.*

[109] *Id.*

[110] *Id.* at *12.

[111] *Id.*

[112] *Id.* at *13.

[113] Notice, AstraZeneca Pharms. v. Becerra, No. 24-1819 (3d Cir. May 2, 2024), ECF No. 1.

[114] Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), *appeal filed*, Novo Nordisk, Inc. v. Becerra, No. 24-2510 (3d Cir. Aug. 19, 2024), ECF No. 1.

claims that CMS wrongfully selected a biologic that had not been approved for 11 years, incorrectly aggregated its product sales in order to determine its "high spend" status, and blurred the lines between Medicare Parts B and D, the court found that the IRA's provision precluding judicial review divested the court of jurisdiction over these claims.[115] The court reviewed the statute's directive that CMS's "selection of drugs," the agency's "determination of negotiation-eligible drugs," and its "determination of qualifying single source drugs" were not subject to administrative or judicial review.[116] The court ruled that it did not have subject matter jurisdiction over Novo Nordisk's first three claims, because they related to the agency's "underlying determinations that led to its identification" of the manufacturer's selected drug, and CMS's selection of drugs was precluded from judicial review.[117] Further, the court characterized the IRA's limitation on judicial review as "an express statutory preclusion" that effectively prohibited ultra vires review.[118] In support of this holding, the court cited a 2022 D.C. Circuit decision explaining that review of an ultra vires claim "is available where (i) there is no express statutory preclusion of all judicial review; (ii) 'there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory[.]'"[119]

With respect to Novo Nordisk's claim that CMS exceeded the IRA's limit of 10 selected drugs for price year 2026, the court found that the drugmaker lacked standing to bring this challenge, which was not precluded by the statute's limitation on judicial review.[120] The court observed that the company's complaint concluded with a "general prayer for relief based on all of their claims," and it found this requested relief "overbroad."[121] The court said the manufacturer was attempting to enjoin CMS from implementing the IRA "as a whole and to declare invalid CMS's entire guidance" and that, as such, the drugmaker failed to demonstrate standing.[122] Novo Nordisk appealed the district court's ruling to the U.S. Court of Appeals for the Third Circuit.[123]

[115] *Id.* at *3.

[116] *Id.*

[117] *Id.*

[118] *Id.*

[119] Fed. Express Corp. v. United States Dep't of Com., 39 F.4th 756, 764 (D.C. Cir. 2022) (quoting Nyunt v. Chairman, Broad. Bd. of Governors, 589 F.3d 445, 449 (D.C. Cir. 2009)).

[120] Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), at *4. The court observed that the directive to select 10 products is found in 42 U.S.C. § 1320f-1(a)(1), which is not listed as one of the sections exempt from administrative or judicial review. *Id.*; *see also* 42 U.S.C. § 1320f-7.

[121] Novo Nordisk, Inc. v. Becerra, No. 23-CV-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), at *4.

[122] *Id.*

[123] Notice, Novo Nordisk v. Becerra, No. 24-2510 (3d Cir. Aug. 19, 2024), ECF No. 1.

Considerations for Congress

As litigation over the Medicare Drug Price Negotiation Program continues to unfold, many observers are keeping a close eye on both the constitutional and APA arguments being made in the cases.[124] Several of the manufacturers' arguments challenging CMS's guidance seem to raise larger questions, including how much leeway an agency should have to interpret a statute and how specific Congress needs to be when delegating authority to an agency to carry out a new program, limiting judicial review, or directing an agency to carry out a particular authority via guidance. Some law firms representing drug manufacturers suggest that the Supreme Court's recent ruling in *Loper Bright Enterprises v. Raimondo*[125] could have implications for drug manufacturers seeking to challenge CMS's interpretations of the statute and, in fact, may even encourage them to bring such suits.[126] For example, one firm suggests that a challenge could emerge over CMS's interpretation of the statute's directive to consider a drug's clinical benefit in its calculation of an initial offer.[127]

The extent to which such challenges over CMS's interpretation of the IRA may be brought, however, depends largely on how those challenges are pled by the plaintiffs and how the courts interpret the IRA's prohibition on administrative and judicial review. As demonstrated in the *AstraZeneca* and *Novo Nordisk* cases, for example, any plaintiff challenging CMS's interpretation of the statute will first need to demonstrate that it has actually suffered harm as a result of the guidance for purposes of satisfying Article III standing. Theoretical arguments that generally address how a manufacturer might be harmed in the future will likely be insufficient to establish such standing.[128] Assuming that Article III standing is satisfied, a reviewing court may find, as was the case in *Novo Nordisk*, that because the specific legal challenge sufficiently relates to CMS's selection of the drug for price negotiation and/or its calculation of the MFP, the court lacks subject matter jurisdiction over the case due to the statute's preclusion of judicial review for some of CMS's determinations under the statute.

[124] O'Neill Institute, *Health Care Litigation Tracker*, GEORGETOWN UNIVERSITY LAW CENTER, https://litigationtracker.law.georgetown.edu/issues/inflation-reduction-act/ (last visited Nov. 13, 2024).

[125] 144 S. Ct. 2244 (2024). *See* CRS Legal Sidebar LSB11189, *Supreme Court Overrules Chevron Framework*, by Benjamin M. Barczewski (2024).

[126] *See*, *e.g.*, Meenakshi Datta et al., *Potential Implications of Loper Bright for the Healthcare Industry*, SIDLEY (July 2, 2024), https://www.sidley.com/en/insights/newsupdates/2024/07/potential-implications-of-loper-bright-for-the-healthcare-industry; *see also* Jamie Gregorian et al., *Loper Bright v. Raimondo: What Life Sciences Companies Should Consider*, DLA PIPER (July 22, 2024), https://www.dlapiper.com/en/insights/publications/2024/07/loper-bright-v-raimondo-what-life-sciences-companies-should-consider.

[127] Jamie Gregorian et al., *Loper Bright v. Raimondo: What Life Sciences Companies Should Consider*, DLA PIPER (July 22, 2024), https://www.dlapiper.com/en/insights/publications/2024/07/loper-bright-v-raimondo-what-life-sciences-companies-should-consider.

[128] *See* Lujan v. Defenders of Wildlife, 504 U.S. 555, 556 (1992) ("Affidavits of members claiming an intent to revisit project sites at some indefinite future time . . . do not suffice, for they do not demonstrate an 'imminent' injury.").

Both the *AstraZeneca* and *Novo Nordisk* appeals are pending before the Third Circuit, as are other rulings from district courts in the *Janssen Pharms. v. Becerra*, *Bristol Myers Squibb Co. v. Becerra*,[129] and *Novartis Pharms. Corp. v. Becerra* cases,[130] all of which challenged the IRA and the Medicare Drug Price Negotiation Program on constitutional grounds. The Third Circuit heard oral arguments in *AstraZeneca*, *Bristol Myers Squibb*, and *Janssen* on October 30, 2024.[131] Fifteen Democratic Members of the Senate filed an amicus brief before the Third Circuit in support of HHS in the *AstraZeneca* case, arguing that "Congress carefully considered the competing interests at stake in the Program and struck an appropriate balance."[132] The amicus brief further insists that the negotiation authority that Congress gave to the Secretary through the IRA was intended to "help[] the Secretary contain these ballooning [Medicare] costs and preserve the health of the Medicare Program for future generations of American seniors."[133]

The outcome of the litigation may have a substantial impact on how CMS will be able to carry out the Program and uphold its stated goals of lowering the prices that Medicare pays for selected drugs.

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Disclaimer

[129] On May 6, 2024, Bristol Myers Squibb and Janssen appealed the district court's summary judgment rulings in their cases to the U.S. Court of Appeals for the Third Circuit. Notice, Bristol Myers Squibb Co. v. Becerra, No. 24-1820 (3d Cir. May 6, 2024), ECF No. 1; Notice, Janssen Pharms. v. Becerra, No. 24-1821 (3d Cir. May 6, 2024), ECF No. 1. The Third Circuit consolidated the appeals. Order, Bristol Myers Squibb Co. & Janssen Pharms. v. Becerra, Nos. 24-1820, 24-1821 (3d Cir. May 6, 2024), ECF No. 4.

[130] Notice, Novartis Pharms. Corp. v. Becerra, No. 24-2968 (3d Cir. Oct. 22, 2024), ECF No. 1.

[131] Order, AstraZeneca Pharms LP. v. Becerra, No. 24-1819 (3d Cir. Oct. 8, 2024), ECF No. 74; Order, Bristol Myers Squibb Co. & Janssen Pharms. v. Becerra, Nos. 24-1820, 24-1821 (3d Cir. May 6, 2024), ECF No. 176. As of the date of this writing, the court has not yet scheduled oral argument in the *Novo Nordisk* or *Novartis* cases.

[132] *See* AstraZeneca Pharms LP. v. Becerra, No. 24-1819 (3d Cir. Sept. 16, 2024), ECF No. 51, at 17.

[133] *Id.* at 18–19.