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Legal Sidebar

Administrative Procedure Act Challenges to CMS's Implementation of the Medicare Drug Price Negotiation Program

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Congress created the Medicare Drug Price Negotiation Program (the program) in 2022 through a budget reconciliation measure known as the Inflation Reduction Act (IRA). 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 (physician administered drugs) and Medicare Part D (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." 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.

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. CMS began implementing the program by issuing Initial Guidance in March 2023, which was subsequently updated in Revised Guidance in June 2023. In accordance with the statute, 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.

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 nine lawsuits have challenged the constitutionality of the program on various grounds, including under the First, Fifth, and Eighth Amendments. In addition to these and other constitutional arguments, AstraZeneca and Novo Nordisk also claim that CMS's implementation of the program violates the Administrative Procedure Act (APA).

This Sidebar explains the APA arguments made in AstraZeneca and Novo Nordisk's cases. (For more information on the constitutional claims, *see* CRS Report R47682, *Constitutional Challenges to the Medicare Drug Price Negotiation Program*). In both cases, the pharmaceutical companies and the government have filed cross motions for summary judgment. In AstraZeneca's case, the Delaware district court heard oral argument on the parties' cross motions for summary judgment on January 31, 2024, but

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has not yet issued a decision. In Novo Nordisk's case, the parties are scheduled to file briefs for their motions for summary judgment through the end of March 2024.

Legal Background

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." 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." Additionally, agency actions that are characterized as "ultra vires" may also be reviewed under the APA. 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.

Defining a Qualifying Single Source Drug

Before selecting the first ten drugs for negotiation, the Secretary of HHS identified the pool of "qualifying single source drugs" (QSSD) in accordance with the statute. For price year 2026, for a small molecule drug to be a QSSD, 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. For a biologic to be a QSSD, 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.

After CMS identified the QSSDs, it calculated the Medicare program'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. The 50 drugs with the highest expenditures were considered "negotiation-eligible drugs." 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." After applying any relevant statutory exceptions, CMS then selected the top 10 highest-spend Medicare drugs for negotiation. (For more specific information on how drugs are selected, *see* CRS Report R47555, *Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations*.)

In its Initial Guidance, CMS stated it would apply the data aggregation provision discussed above to the definition of what it considered a single QSSD. CMS stated 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. 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)," 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. 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." While some stakeholders 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.

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." CMS advised that the agency "intends to monitor whether robust and meaningful competition exists in the market." 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.

Drug Manufacturers' Motions for Summary Judgment

AstraZeneca's Arguments

Both AstraZeneca and Novo Nordisk have challenged CMS's definition of QSSD and the bona fide marketing requirement under the APA. In its motion for summary judgment, AstraZeneca argues 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. The drugmaker claims 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. AstraZeneca argues that QSSDs should be based on an NDA or BLA, not on active ingredients, because the IRA definition of QSSD references the definition of a "covered Part D drug" in the Medicare statute, which, in turn, references the definition of "covered outpatient drug" in the Medicaid statute, which is tied to a drug product's distinct NDA or BLA. The company further alleges that the effects of CMS's QSSD policy "will 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. AstraZeneca also says that the QSSD definition is arbitrary and capricious because it "discourages" manufacturers from improving their existing products.

With respect to the bona fide marketing requirement, AstraZeneca claims that CMS's interpretation is contrary to the plain language of the IRA as well as arbitrary and capricious. The manufacturer argues that "[n]owhere in the law did Congress include qualifying language that might narrow or otherwise change the ordinary meaning of the word 'marketed.'" AstraZeneca describes the IRA's marketing requirement as a "check-the-box inquiry," and points to an existing Medicaid Drug Rebate Program policy that defines "marketed" by reference to when a product is available for sale. The company also argues that in *Asgrow Seed Co. v. Winterboer*, the Supreme Court found that the term marketing "ordinarily refers to the act of holding forth property for sale." AstraZeneca claims that CMS's "holistic" and "totality of the circumstances" inquiry is too subjective and as a result of CMS's bona fide marketing requirement, a product's price could be subject to negotiation while also being subject to generic competition.

Novo Nordisk's Arguments

Novo Nordisk takes 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 and by selecting QSSDs that have generic or biosimilar competition. The drug maker argues 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 ten drugs for price year 2026. Similar to AstraZeneca, Novo Nordisk says 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."

The company also argues that CMS's focus on the active moiety, 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. The manufacturer points 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. Novo also argues 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).

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 asserts that AstraZeneca lacks standing to bring the APA challenges, because the company did not demonstrate that the QSSD definition impacted Farxiga's selection. According to the government, Farxiga is manufactured under a single NDA, has one dosage form, two strengths, and no currently approved, generic competitors. Thus, the government says, AstraZeneca was not actually harmed by CMS's interpretation of the QSSD definition and lacks standing to challenge it.

The government next argues that the plain text of the IRA precludes judicial review of both AstraZeneca and Novo Nordisk's claims, including their ultra vires challenges. The government relies 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. The government points 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. 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 intwined" with the estimate itself. Even though the hospital argued that the action was reviewable under the APA as ultra vires, the court disagreed, finding that CMS's payment methodology was not an "obvious violation of a clear statutory command." The government makes similar arguments in its summary judgment motions against AstraZeneca and Novo Nordisk, arguing 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 intwined" with the selection itself and thus should fail.

On the merits, the government argues in both cases that using active moieties and ingredients in the QSSD definition does not violate the IRA. 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. The government characterizes the manufacturers' interpretation of the data-aggregation provision as "nonsensical" and asserts that the Revised Guidance is not arbitrary or capricious because CMS reasonably explained its approach to the QSSD definition. The government claims 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 applies for FDA approval. The government points 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 argues that these references "would make no sense if Congress had intended CMS to follow FDA's product-specific approach." The government further reasons 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.

With respect to Novo Nordisk's argument that the QSSD conflates Part B and Part D drugs in violation of the statute, the government says 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." 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. The government argues NovoLog meets both criteria and thus that the drug is not exempted from selection simply because it also receives reimbursement under Part B.

Lastly, the government argues that CMS's bona fide marketing standard is consistent with the IRA. The government explains that the standard is needed to ensure that manufacturers cannot avoid the Negotiation Program by contracting with a generic competitor to launch a *de minimus* amount of a generic drug or biosimilar, thereby exempting it from the QSSD definition. The government also argues 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." The government also disputes 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.

Considerations for Congress

As litigation over the Medicare Drug Price Negotiation continues to unfold, many observers are keeping a close eye on both the constitutional and APA arguments being made in the cases. 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 limiting judicial review or directing an agency to issue guidance. A variety of stakeholders and a few Members of Congress have expressed direct interest in the legal developments or have requested leave to file amicus briefs. Absent additional action from Congress, the outcome of the litigation may have a substantial impact on how effectively CMS will be able to carry out the program and uphold its stated goals of lowering drug prices for Medicare beneficiaries.

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