

Table – Litigation Regarding CMS Drug Pricing Negotiation Authority

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The [Inflation Reduction Act \(IRA\) of 2022](#), signed into law on August 16, 2022, contains numerous provisions aiming to lower the cost of select prescription drugs for Medicare beneficiaries and the federal government. IRA authorizes the Medicare Drug Price Negotiation Program (DPP), which requires the Secretary of Health and Human Services (HHS) to negotiate drug prices with manufacturers for certain Medicare Part D drugs over years ahead.¹ On August 29, 2023, the Centers for Medicare & Medicaid Services (CMS) announced [initial drugs](#) chosen for negotiation representing the “top 10” eligible Part D drugs with the highest Medicare expenditures over the prior year.² Manufacturers’ negotiations with CMS are anticipated to lead to new, posted drug prices by September 1, 2024. Negotiated prices will take effect on January 1, 2026.³ For more information, see recent commentary published on September 20, 2023 in the Journal of the American Medical Association (JAMA).⁴

Prior to CMS’ selection, several drug manufacturers (and others) filed lawsuits questioning the constitutionality of IRA provisions. Most of the plaintiffs are drug manufacturers claiming standing to sue based on their drug’s status among CMS’ initial “top 10” list. Some of the suits were withdrawn after CMS issued its list; others have since been raised. This Table summarizes *ongoing litigation* surrounding CMS DPP as per the following information in **Columns**:

- I. chronologically lists case names and numbers, hyperlinks to the complaint (where available), and **date** filed;
- II. identifies the court where the complaint was filed;
- III. provides brief case status updates and filing dates;
- IV. describes factual angles of the suits (drugs selected via CMS’ 8/29 DPP announcement are **highlighted**); and
- V. delineates primary constitutional arguments raised in each case by **plaintiffs** and **defendants**.

I. Case & Date	II. Court	III. Status	IV. Factual Angle	V. Constitutional Arguments
Merck v. Becerra et al. , No. 1:23-CV-01615 June 6, 2023	U.S. District Court for the District of Columbia	Defendant's Reply Brief Supporting Motion for Summary Judgment - 11/29/23	<p>Plaintiffs: Allege that CMS DPNP is coercive and does not constitute genuine negotiations. Standing is based on the manufacturing of Januvia, Janumet, and Keytruda.</p> <p>Defendants: Argue that Takings Clause and Compelled Speech arguments fail because participation in Medicare and the DPNP is voluntary, and no physical or regulatory taking has occurred.</p>	<p>Plaintiffs: 1st Amendment - Compelled Speech 5th Amendment - Takings Unconstitutional Conditions</p> <p>Defendants: Standing Ripeness 1st Amendment- Compelled Speech 5th Amendment- Takings Unconstitutional Conditions Doctrine</p>
Dayton Area Chamber of Commerce et al. v. Becerra et al. , No. 3:23-cv-00156 June 9, 2023	U.S. District Court for the Southern District of Ohio Western Division	Defendant's Motion to Dismiss and Cross-Motion for Summary Judgment - 12/15/23	<p>Plaintiffs: Claim associational standing because the chambers of commerce involve pharmaceutical companies that are subject to IRA provisions. One of the chambers' members manufactures Imbruvica.</p>	<p>Plaintiffs: 1st Amendment - Compelled Speech 5th Amendment - Due Process 8th Amendment - Excessive Fines Separation of Powers - Nondelegation Doctrine Congressional Authority</p> <p>Defendants: Standing; Ripeness</p>
Bristol-Myers Squibb Co. v. Becerra et al. , No. 3:23-cv-03335	U.S. District Court for the District of New Jersey	Plaintiff's Reply in Support of Motion for Summary	<p>Plaintiffs: Allege that CMS' DPNP results in a scheme where HHS dictates a price that compels drug companies to sell their most lucrative and innovative drugs or face steep</p>	<p>Plaintiffs: 1st Amendment - Compelled Speech 5th Amendment – Takings</p>

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June 16, 2023	Trenton Vicinage	Judgment - 11/24/23	<p>penalties. Standing is based on the manufacturing of Opdivo and Eliquis.</p> <p>Defendants: Argue that Takings Clause & Compelled Speech arguments fail because participation in Medicare & DPNP is voluntary as manufacturers can withdraw from negotiations. Argues that plaintiffs have no property interest in Medicare sales to constitute a taking.</p>	<p>Unconstitutional Conditions Doctrine</p> <p>Defendants: 1st Amendment – Compelled Speech 5th Amendment- Takings Unconstitutional Conditions Doctrine</p>
Nat'l Infusion Ctr. Ass'n et al. v. Becerra et al. , No: 23-cv-00707 June 21, 2023	U.S. District Court for the Western District of Texas Austin Division	Plaintiff's Motion for leave to file response to Defendants' Notice of Supplemental Authority -11/7/23	<p>Plaintiffs: Allege that DPNP does not involve genuine negotiation and is insulated from accountability through failing to require notice-and-comment rulemaking and limiting the information that may be disclosed regarding negotiations.</p> <p>Standing is based on the following: Infusion Association members, like BioTek, receive reimbursement revenue from drugs and treatments, like Stelara. Global Colon Cancer Association members rely on cancer drugs subject to negotiation.</p> <p>PhRMA members manufacture drugs expected to be selected for negotiation such as Eliquis, Xarelto, Januvia, Jardiance, Imbruvica, Novolog, Xtandi, Enbrel, Myrbetriq, and Spiriva.</p> <p>Defendants: Argue that plaintiffs lack standing due to the approval of a biosimilar</p>	<p>Plaintiffs: 5th Amendment – Due Process 8th Amendment - Excessive Fines Separation of Powers - Nondelegation Doctrine</p> <p>Defendants: Subject Matter Jurisdiction- Medicare Act Standing Venue Separation of Powers- Nondelegation Doctrine 8th Amendment- Excessive Fines</p>

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			for Stelara which disqualifies the drug from DPNP.	
Janssen Pharmaceuticals v. Becerra et al. , No: 23-cv-03818 July 18, 2023	U.S. District Court for the District of New Jersey Trenton Vicinage	Plaintiff's Reply in Support of Motion for Summary Judgment - 11/24/23	<p>Plaintiffs: Allege that DPNP is a mandated price control (and not negotiation) that is unconstitutional and a public policy mistake. Standing is based on the manufacturing of Xarelto.</p> <p>Defendants: Argue that Takings Clause and Compelled Speech arguments fail because participation in Medicare and the DPNP is voluntary, and manufacturers have adequate opportunity to withdraw from negotiations. Argues that plaintiffs have no property interest in Medicare sales to constitute a taking.</p>	<p>Plaintiffs: 1st Amendment- Compelled Speech 5th Amendment – Takings Unconstitutional Conditions Doctrine</p> <p>Defendants: 1st Amendment – Compelled Speech 5th Amendment- Takings Unconstitutional Conditions Doctrine</p>
Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. HHS et al. , No. 3:23-cv-01103 August 18, 2023	U.S. District Court for the District of Connecticut	Defendant's Opposition to Plaintiff's Motion for Summary Judgment and Cross-Motion - 12/20/23	<p>Plaintiffs: Allege that DPNP (1) fundamentally alters the U.S. health care market and that manufacturers have no genuine choice in negotiating; and (2) presents a conflict of interest between CMS's dual role as price-setting entity and payor. Standing is based on the manufacturing of Jardiance.</p>	<p>Plaintiffs: 1st Amendment - Compelled Speech 5th Amendment - Due Process & Takings 8th Amendment - Excessive Fines Separation of Powers Unconst. Conditions Doctrine</p>
AstraZeneca Pharmaceuticals v. Becerra et al. , 1:23-cv-00931 August 25, 2023	U.S. District Court for the District of Delaware	Plaintiff's Brief in Opposition to Defendant's Cross-Motion for Summary	<p>Plaintiffs: Allege the IRA undermines the Orphan Drug Act by reducing incentives for development of new drugs and that the definitions of "Qualifying Single Source Drug" and "Bona Fide Marketing" are arbitrary and capricious under the Administrative Procedures Act. Standing is</p>	<p>Plaintiffs: 5th Amendment -Due Process</p> <p>Defendants: Standing Administrative Procedure Act Subject Matter Jurisdiction</p>

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		Judgement & Reply in Support of Plaintiffs' Motion for Summary Judgment - 12/1/23	based on the manufacturing of Lynparza, Soliris, Farxiga, and Calquence.	5th Amendment- Due Process
Novartis Pharmaceuticals Corp. v. Becerra et al. , 2:23-cv-14221 September 1, 2023	U.S. District Court for the District of New Jersey	Plaintiff's Motion for Summary Judgment - 11/22/23	Plaintiffs: Allege that the IRA is a “forced-sales regime” that harms innovation and deprives manufacturers of market price for their “lifechanging” drugs. Standing is based on the manufacturing of Entresto.	Plaintiffs: 1st Amendment – Compelled Speech 5th Amendment – Takings 8th Amendment – Excessive Fines Unconstitutional Conditions Doctrine
Novo Nordisk Inc. v. Becerra et al. , 3:23-cv-20814 September 29, 2023	U.S. District Court for the District of New Jersey	Plaintiff's Motion for Summary Judgment - 12/8/23	Plaintiffs: Allege that CMS extended IRA's “already unprecedented price controls” beyond Congress' authorization through their selection of eligible drug products, negotiation procedures, and implementation of agency guidance. Standing is based on the manufacturing of NovoLog products and FIASP products.	Plaintiffs: 1st Amendment- Compelled Speech 5th Amendment- Due Process Separation of Powers- Non-Delegation Doctrine Exceeding Congressional Authority- Ultra Vires

Source: Select court documents were accessed through [CourtListener](#).

¹ 42 U.S.C.A. § 1320f.

² CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026* (June 30, 2023), <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>.

³ 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

⁴ Gostin LO, Hodge JG, Twinamatsiko A. [Medicare's historic prescription drug price negotiations](#). *JAMA*. 2023; (online September 20).