

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, seeks 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 result in new drug prices by September 1, 2024, which then take effect on January 1, 2026.^{3,4}

Prior to CMS’ selection, several drug manufacturers (and others) sued to question the constitutionality of IRA provisions. While some initial suits were withdrawn after CMS issued its list, others have since been raised.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), **date** filed, and identifies the court where the complaint was filed;
- II. provides brief case status updates and filing dates;
- III. describes factual angles of the suits (drugs selected via CMS’ 8/29 DPP announcement are **highlighted**); and
- IV. delineates primary constitutional arguments raised in each case by **plaintiffs** and **defendants**.

I. Case, Ct. & Date	II. Status	III. Factual Angle	IV. Constitutional Arguments
<p>Merck v. Becerra et al., No. 1:23-CV-01615</p> <p>U.S. District Court for the District of Columbia</p> <p>June 6, 2023</p>	<p>Plaintiff's Response to Defendant's Notice of Supplemental Authority - 3/4/24</p>	<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 Doctrine</p> <p>Defendants: Standing; Ripeness 1st Amendment – Compelled Speech 5th Amendment – Takings Unconstitutional Conditions Doctrine</p>
<p>Dayton Area Chamber of Commerce et al. v. Becerra et al., No. 3:23-cv-00156</p> <p>U.S. District Court for the Southern District of Ohio</p> <p>June 9, 2023</p>	<p>Plaintiff's Response to Defendant's Notice of Supplemental Authority - 3/7/24</p>	<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>Defendants: Argue that plaintiffs lack associational standing because lawsuit is not germane to chamber's "organizational purpose" and individual members are not participating. Argue that Due Process and Compelled Speech arguments fail because DPNP is voluntary and manufacturers are not required to reach an agreement, and Excessive Fines claim fails because the excise tax is authorized under Congress' taxing powers.</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: 1st Amendment – Compelled Speech 5th Amendment – Due Process 8th Amendment – Excessive Fines Standing; Ripeness; Venue Subject Matter Jurisdiction Separation of Powers – Nondelegation Doctrine</p>
<p>Bristol-Myers Squibb Co. v. Becerra et al., No. 3:23-cv-03335</p> <p>U.S. District Court for the District of</p>	<p>Defendant's Reply in Support of Motion for Summary Judgment – 12/22/23</p> <p>Oral Argument – 3/7/24</p>	<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 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</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>

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<p>New Jersey Trenton Vicinage</p> <p>June 16, 2023</p>		<p>from negotiations. Argues that plaintiffs have no property interest in Medicare sales to constitute a taking and Congress may set conditions on Medicare participation.</p>	
<p>Nat'l Infusion Ctr. Ass'n et al. v. Becerra et al., No: 23-cv-00707</p> <p>U.S. District Court for the Western District of Texas Austin Division</p> <p>June 21, 2023</p>	<p>Appeal filed in U.S. Court of Appeals for Fifth Circuit – 3/14/24</p>	<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. PhRMA members manufacture drugs selected for negotiation including Eliquis, Xarelto, Januvia, Jardiance, Imbruvica, Novolog, and Enbrel.</p> <p>Defendants: Argue that plaintiffs lack standing due to the approval of a biosimilar for Stelara which disqualifies the drug from DPNP. Argue the court lacks subject matter jurisdiction because plaintiffs did not exhaust administrative remedies under Medicare Act.</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>
<p>Janssen Pharmaceutical als v. Becerra et al., No: 23-cv-03818</p> <p>U.S. District Court for the District of New Jersey</p>	<p>Oral Arguments – 3/7/24</p>	<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 can withdraw from negotiations. Plaintiffs arguably 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>

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Trenton Vicinage July 18, 2023		In addition, Congress may set conditions on Medicare participation.	
Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. HHS et al. , No. 3:23-cv-01103 U.S. District Court for the District of Connecticut August 18, 2023	Defendant’s Notice of Supplemental Authority– 3/4/24	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. Administrative Procedures Act violations are also alleged. Standing is based on the manufacturing of Jardiance . Defendants: Argue that participation in Medicare and DPNP is voluntary, DPNP is a proper condition on receipt of federal funds, and that plaintiffs have no property interest in Medicare reimbursement rates. Excessive fines arguments arguably fail on subject-matter jurisdiction and merit grounds.	Plaintiffs: 1st Amendment – Compelled Speech 5th Amendment – Due Process & Takings 8th Amendment – Excessive Fines Separation of Powers Unconstitutional Conditions Doctrine Defendants: 1st Amendment – Compelled Speech 5th Amendment – Takings & Due Process 8th Amendment – Excessive Fines Subject Matter Jurisdiction – 8 th Amendment
AstraZeneca Pharmaceuticals v. Becerra et al. , 1:23-cv-00931 U.S. District Court for the District of Delaware August 25, 2023	Summary judgment granted in government’s favor for lack of jurisdiction and as a matter of law – 3/1/24	Plaintiffs: Allege CMS’ issuance of guidance documents to implement DPNP violates the Administrative Procedures Act; definitions of “Qualifying Single Source Drug” and “Bona Fide Marketing” are arbitrary and capricious. Standing is based on the manufacturing of Lynparza, Soliris, Farxiga , and Calquence. Defendants: Argue that Due Process claims fail because participation in Medicare is voluntary and thus no protected property interest is deprived.	Plaintiffs: 5th Amendment – Due Process Exceeding Congressional Authority – Ultra Vires Defendants: Standing Administrative Procedure Act Subject Matter Jurisdiction 5th Amendment – Due Process
Novartis Pharmaceuticals	Oral Argument – 3/7/24	Plaintiffs: Allege that the IRA is a “forced-sales regime” that harms innovation and deprives manufacturers of	Plaintiffs: 1st Amendment – Compelled Speech

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<p>Is Corp. v. Becerra et al., 2:23-cv-14221</p> <p>U.S. District Court for the District of New Jersey</p> <p>September 1, 2023</p>		<p>market price for their “lifechanging” drugs. Standing is based on the manufacturing of Entresto.</p> <p>Defendants: Participation in Medicare and DPNP is voluntary and not coercive, DPNP is a proper condition on receipt of federal funds, and drug manufacturers have no property interest in Medicare reimbursement rates. Excessive fines arguments fail on subject-matter jurisdiction and merit grounds.</p>	<p>5th Amendment – Takings 8th Amendment – Excessive Fines Unconstitutional Conditions Doctrine</p> <p>Defendants: 1st Amendment – Compelled Speech 5th Amendment – Takings Subject Matter Jurisdiction – 8th Amendment Excessive Fines</p>
<p>Novo Nordisk Inc. v. Becerra et al., 3:23-cv-20814</p> <p>U.S. District Court for the District of New Jersey</p> <p>September 29, 2023</p>	<p>Oral Argument – 3/7/24</p>	<p>Plaintiffs: Allege that CMS extended IRA’s “already unprecedented price controls” beyond Congress’ authorization through selection of eligible drug products, negotiation procedures, and implementation of agency guidance. Administrative Procedure Act violations arguably arise. Standing is based on the manufacturing of NovoLog products and FIASP products.</p> <p>Defendants: Argue that 1st and 5th Amendment claims fail because Medicare and DPNP are voluntary programs and by participating, drug manufacturers are neither deprived of any property interest nor forced to speak. Argue that DPNP is a properly executed program under Congress’s spending authority.</p>	<p>Plaintiffs: 1st Amendment – Compelled Speech 5th Amendment – Due Process Separation of Powers – Non-Delegation Doctrine Exceeding Congressional Authority – Ultra Vires</p> <p>Defendants: Subject Matter Jurisdiction Merit of Claims 1st Amendment – Compelled Speech 5th Amendment – Takings, Due Process Separation of Powers- Nondelegation Doctrine</p>

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).