

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 (DPNP), 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. 42 U.S.C.A. § 1320f. On August 29, 2023, the Centers for Medicare & Medicaid Services (CMS) announced the [first 10 drugs](#) chosen for negotiation representing the “top 10” eligible Part D drugs with the highest Medicare expenditures over the prior year.¹ Manufacturers of these drugs must sign an agreement to negotiate by October 1, 2023, with negotiations leading to CMS’ posted drug prices by September 1, 2024. Negotiated prices will take effect on January 1, 2026.²

Prior to CMS’ selection, several drug manufacturers (and others) filed lawsuits questioning the constitutionality of IRA provisions. Manufacturers claim standing to sue based on their drug’s likely status as a “top 10” Part D drug. This Table summarizes ongoing litigation surrounding IRA’s drug negotiation provisions 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;
- IV. describes factual angles of the suits (drugs selected via CMS’ 8/29 DPNP announcement are **highlighted**); and
- V. delineates primary constitutional arguments raised in each case by each party.

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	Plaintiff's Opposition to Motion to Dismiss filed on August 25, 2023	Alleges that CMS DPNP is coercive and does not constitute genuine negotiations. Standing is based on the manufacturing of Januvia , Janumet, and Keytruda.	Plaintiffs: First Amendment - Compelled Speech Fifth Amendment - Takings Clause
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	Defendants' Opposition for Motion for Preliminary Injunction filed on August 11, 2023	Plaintiffs claim associational standing because chambers of commerce involve pharmaceutical companies that are subject to IRA provisions. One of the chambers' members manufactures Imbruvica .	Plaintiffs: First Amendment - Compelled Speech Fifth Amendment - Due Process (Procedural) Eighth Amendment - Excessive Fines Clause Separation of Powers - Nondelegation Doctrine Exceeding Congressional Authority Defendants: Standing Ripeness
Bristol-Myers Squibb Co. v. Becerra et al. , No. 3:23-cv-03335 June 16, 2023	U.S. District Court for the District of New Jersey Trenton Vicinage	Motion for Summary Judgment filed August 16, 2023	Alleges 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 .	Plaintiffs: First Amendment - Compelled Speech Fifth Amendment - Takings Clause Unconstitutional Conditions Doctrine

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<p>Nat'l Infusion Ctr. Ass'n et al. v. Becerra et al., No: 23-cv-00707</p> <p>June 21, 2023</p>	<p>U.S. District Court for the Western District of Texas Austin Division</p>	<p>Motion for Summary Judgment filed on August 10, 2023</p>	<p>Alleges 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 receive reimbursement revenue from drugs and treatments likely included in Program. Global Colon Cancer Association members rely on cancer drugs subject to negotiation. 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>Plaintiffs:</p> <p>Fifth Amendment - Due Process (Procedural)</p> <p>Eighth Amendment - Excessive Fines Clause</p> <p>Separation of Powers - Nondelegation Doctrine</p>
<p>Astellas Pharma US, Inc. v. U.S. Department of Health and Human Services et al., No: 23-cv-04578</p> <p>July 14, 2023</p>	<p>U.S. District Court for the Northern District of Illinois Eastern Division</p>	<p>Joint Motion for Briefing Schedule filed on August 25, 2023</p>	<p>Alleges that DPNP does not constitute genuine negotiations and that government-mandated pricing will stifle innovation and reduce the availability of life-saving drugs.</p> <p>Standing is based on the manufacturing of Xtandi and Myrbetriq.</p>	<p>Plaintiffs:</p> <p>First Amendment - Compelled Speech</p> <p>Fifth Amendment - Takings Clause and Due Process</p>
<p>Janssen Pharmaceuticals, Inc. v. Becerra et al., No: 23-cv-03818</p>	<p>U.S. District Court for the District of New Jersey</p>	<p>Plaintiff's Motion for Summary Judgment Filed on</p>	<p>Alleges that DPNP is a mandated price control (and not negotiation) that is unconstitutional and a public policy mistake.</p>	<p>Plaintiffs:</p> <p>First Amendment - Compelled Speech</p> <p>Fifth Amendment - Takings Clause</p>

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July 18, 2023	Trenton Vicinage	August 16, 2023	Standing is based on the manufacturing of Xarelto .	
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	Complaint Filed	Alleges 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 .	Plaintiffs: Fifth Amendment - Due Process Clause and Takings Clause First Amendment - Compelled Speech Eighth Amendment - Excessive Fines Separation of Powers Unconstitutional Conditions Doctrine
AstraZeneca Pharmaceuticals LP v. Becerra et al. , 1:23-cv-00931 August 25, 2023	U.S. District Court for the District of Delaware	Complaint Filed	Alleges 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 based on the manufacturing of Lynparza, Soliris, Farxiga , Calquence.	Plaintiffs: Fifth Amendment – Substantive and Procedural Due Process

Source: Court documents were accessed through [Georgetown University O’Neill Institute Health Care Litigation Tracker](#).

¹ 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), [chrome-extension://efaidnbmnmbpcjpcglclefindmkaj/https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf](https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf).

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