

Table – Litigation Regarding CMS Drug Pricing Negotiation Authority

JAMES G. HODGE, JR., JD, LL.M.
Director

ERICA N. WHITE, JD
Research Scholar

MARY SAXON
Senior Legal Researcher

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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” drug. Some of the initially-filed suits (e.g., Astellas Pharma claim) have been withdrawn. 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
<p>Merck v. Becerra et al., No. 1:23-CV-01615</p> <p>June 6, 2023</p>	<p>U.S. District Court for the District of Columbia</p>	<p>Defendant's Response to Plaintiff's Motion for Summary Judgment filed on 9/11/23</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 DPNP is voluntary and no physical or regulatory taking has occurred.</p>	<p>Plaintiffs: First Amendment - Compelled Speech Fifth Amendment - Takings Clause</p> <p>Defendants: Standing Ripeness First Amendment- Compelled Speech Fifth Amendment- Takings Clause Unconstitutional Conditions Doctrine</p>
<p>Dayton Area Chamber of Commerce et al. v. Becerra et al., No. 3:23-cv-00156</p> <p>June 9, 2023</p>	<p>U.S. District Court for the Southern District of Ohio Western Division</p>	<p>Defendants' Reply in Support of their Motion to Dismiss filed 9/8/23</p>	<p>Plaintiffs: Plaintiffs claim associational standing because chambers of commerce involve drug companies that are subject to IRA provisions. One of the chambers' members manufactures Imbruvica.</p>	<p>Plaintiffs: First Amendment - Compelled Speech Fifth Amendment – Due Process Clause Eighth Amendment - Excessive Fines Clause Separation of Powers - Nondelegation Doctrine Exceeding Congressional Authority</p> <p>Defendants: Standing Ripeness</p>

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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 on 8/16/23	Plaintiffs: Alleges that 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
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	Motion to Dismiss filed on 8/28/2023	Plaintiffs: 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. 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 selected for negotiation such as Eliquis , Xarelto , Januvia , Jardiance , Imbruvica , Novolog and Enbrel .	Plaintiffs: Fifth Amendment – Due Process Clause Eighth Amendment - Excessive Fines Clause Separation of Powers - Nondelegation Doctrine Defendants: Lack of Subject Matter Jurisdiction Standing Venue
Janssen Pharmaceuticals, Inc. 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 Motion for Summary Judgment filed on 8/16/23	Alleges that DPNP is a mandated, unconstitutional price control (and not a legitimate negotiation). Standing is based on the manufacturing of Xarelto .	Plaintiffs: First Amendment - Compelled Speech Fifth Amendment – Takings Clause Unconstitutional Conditions Doctrine
Boehringer Ingelheim	U.S. District Court for the	Complaint filed	Plaintiffs:	Plaintiffs:

I. Case & Date	II. Court	III. Status	IV. Factual Angle	V. Constitutional Arguments
Pharmaceuticals, Inc. v. U.S. HHS et al. , No. 3:23-cv-01103 August 18, 2023	District of Connecticut		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 .	First Amendment - Compelled Speech Fifth Amendment – Due Process & Takings Clauses 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	Plaintiffs: 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 , and Calquence.	Plaintiffs: Fifth Amendment - Due Process Clause
Novartis Pharmaceuticals Corp. v. Becerra et al. , 2:23-cv-14221 September 1, 2023	U.S. District Court for the District of New Jersey	Complaint filed	Plaintiffs: Alleges 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: First Amendment – Compelled Speech Fifth Amendment – Takings Eighth Amendment – Excessive Fines Unconstitutional Conditions Doctrine

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

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://efaidnbmnnnibpcajpcglclefindmkaj/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).