

The Drug Price Negotiation Program Faces Pushback from Private and Public Industry Participants

Article By:

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This month, pharmaceutical manufacturer, [Merck & Co., Inc.](#) (Merck), as well as [four chambers of commerce](#), have filed suits against the federal government, arguing that the Medicare Drug Price Negotiation Program introduced by the Inflation Reduction Act of 2022 stands in violation of multiple constitutional provisions.

What is the Medicare Drug Price Negotiation Program?

The Inflation Reduction Act (the IRA) was signed into law in August 2022.[1] The legislation implemented three distinct avenues aimed at lowering the price of prescription drugs for Medicare beneficiaries: (i) the Drug Price Negotiation Program, which allows CMS to negotiate with manufacturers for the prices of single-source drugs with the highest expenditure rates under Medicare Part B and Part D; (ii) the restructuring of Part D, which is intended to, among other goals, close the coverage gap, expand eligibility for low-income subsidies, and increase vaccine coverage; and (iii) the Rebate Programs, which require manufacturers to reimburse Medicare if the prices for their Medicare Part B and Part D drugs increase faster than the rate of inflation.

Notably, the Drug Price Negotiation Program imposes a daily excise tax upon drug manufacturers who fail to negotiate successfully with the U.S. Department of Health and Human Services (HHS), which is based on an escalating percentage of the previous year's gross sales of the drug in question, starting at sixty-five percent (65%) and increasing by ten percent (10%) every quarter to a maximum of ninety-five percent (95%).

What are the bases of the recent challenges?

Industry participants have been opposed to the legislation since its enactment and, this month, Merck and four chambers of commerce (collectively, the Complainants) took action by filing suit against the HHS with respect to the Drug Price Negotiation Program.

The Complainants claim that the IRA violates multiple provisions of the U.S. Constitution and that the Drug Price Negotiation Program is nothing more than a unilateral drug price control mandate, even using the word "extortion." The primary concern cited by the Complainants is that the program will restrict free market and hamper innovation for developing new treatments and cures, disincentivizing

pharmaceutical manufacturers from participating in, and investing in, the industry and ultimately, hurting consumers who desperately need the drugs. As stated by the chambers of commerce, limiting drug prices in this way will “disrupt and endanger vital research and development, eliminate jobs, deprive patients of access to life-saving and life-enhancing therapies, increase the overall long-term costs of care, and discourage investment in a sector that is critical for our nation’s security as well as the public health.”

The Complainants both alleged that the Drug Price Negotiation Program violates the First and Fifth Amendments, and the chambers alleged that the program also violates the Eighth Amendment, as well as Article I of the Constitution.

First Amendment Allegation: The Complainants allege that the excise tax effectively coerces pharmaceutical manufacturers into agreeing to a maximum price that they must endorse, against their will, as “fair” pursuant to the negotiations. The Complainants allege that this coerced speech endorsement amounts to a violation of their First Amendment right to free speech, and question why Congress chose this indirect approach instead of simply giving HHS the authority to set drug prices for Medicare beneficiaries.

Fifth Amendment Allegation: The Complainants allege that the Drug Price Negotiation Program violates the Fifth Amendment’s Due Process Clause by depriving pharmaceutical manufacturers of their property without “just compensation” or procedural protections. Pharmaceutical manufacturers have property interests in their investment-backed patented products and are entitled to be free from price controls and to sell their drugs at fair market value. However, as alleged by Merck, the program is designed not to provide fair market value “because it requires HHS to seize minimum discounts from market benchmark prices and grants the agency vast discretion to provide even less remuneration.”

Eighth Amendment Allegation: The chambers of commerce allege that the excise tax imposes “excessive fines” on pharmaceutical manufacturers that amount to punitive action in violation of the Eighth Amendment. “This is no tax,” said the chambers, “it is more like an ax.”

Article I Allegation: The chambers of commerce allege that the Drug Price Negotiation Program grants HHS unchecked power to set pharmaceutical prices in violation of the Separation of Powers Clause included in Article I of the Constitution. The chambers of commerce argue that without discernable legal standards and procedural safeguards, such as formalized opportunities for public input and judicial review, HHS is not held accountable as is required by the Constitution.

What does this mean for the industry?

All eyes will be on the District Court for D.C. and the District Court for the Southern District of Ohio, Western Division, which will be deciding the Merck and chambers’ suits, respectively.

Timing is critical here, as HHS is set to announce the ten products that will be selected for the Drug Price Negotiation Program for FY2026 by September 1 of this year,[2] and Merck’s diabetes drug, Januvia, is expected to be on the list.[3] The litigation will likely be closely watched by other pharmaceutical manufacturers, not the least of which will be the other nine manufacturers chosen for participation in the Drug Price Negotiation Program for FY2026.

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FOOTNOTES

[1] Inflation Reduction Act, P.L. 117-169 (2022). Please refer to [our summary](#) of the IRA.

[2] See [Medicare Drug Price Negotiation Program Timeline](#), CMS.

[3] See Merck Complaint at p. 4.

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