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Not Over Yet?: Drug Manufacturers Eye Potential Circuit Split on Federal Drug Pricing Program

The U.S. Court of Appeals may be seriously considering the drug makers' Eighth Amendment challenge given the magnitude of the tax associated with noncompliance with the Drug Price Negotiation Program. A Fifth Circuit decision in the brand manufacturers' favor would create a circuit split on constitutionality of the DPNP and could encourage the Supreme Court to weigh in on the issue.

By **Amy N. Vegari** and **Sarah E. Brand**
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The Inflation Reduction Act's Drug Price Negotiation Program has been the subject of litigation since Congress passed it in 2022 in an effort to curb the cost to Medicare of brand-name pharmaceutical drugs. These challenges—initiated in federal court by major pharmaceutical manufacturers—have largely been unsuccessful, rejected in both federal district and appeals courts in the Second and Third Circuits, with writs of certiorari uniformly denied by the U.S. Supreme Court.

But all hope is not yet lost for pharmaceutical manufacturers' opposition to the DPNP. A few challenges remain pending in the U.S. Courts of Appeals for the District of Columbia and Fifth Circuits, with the latter signaling potential receptiveness to the manufacturers' positions at oral argument. See National Infusion Center Association v. Kennedy, No. 25-50661 (5th Cir. Aug. 15, 2025).

While courts have generally not accepted the arguments that the IRA violates the Administrative Procedure Act, the nondelegation doctrine, the First Amendment, or the Fifth Amendment, the Fifth Circuit may be seriously considering the Eighth Amendment challenge given the magnitude of the tax associated with non-compliance with the DPNP. A Fifth Circuit decision in the brand manufacturers' favor would create a circuit split on constitutionality of the DPNP and could encourage the Supreme Court to weigh in on the issue.

Congress enacted the IRA in response to its finding that purchase prices for branded, patent-protected drug products were driving high pharmaceutical spending in the United States. The IRA fashions the DPNP as the means to achieve reduced Medicare spending on branded prescription drugs.

Through the program, the Center for Medicare and Medicaid Services chooses a specific number of drugs on an annual basis for which it will engage with the drugs' manufacturers in a negotiation process to determine a "maximum fair price" CMS will pay for each selected drug. Only CMS may select the drugs covered by the DPNP. Once CMS publishes the list of selected

drugs for negotiation, the manufacturers of those drugs must decide whether to negotiate and enter into a pricing agreement with CMS.

If a manufacturer of a selected drug wants to participate in Medicare, it must either agree to negotiate or pay an excise tax of at least 65% and up to 95% on all Medicare and non-Medicare sales of that drug.

CMS published guidance applicable only to the 2026 price period on June 30, 2023, after receiving public comment. The guidance included two provisions related to how CMS would determine whether a drug constitutes a "qualifying single source drug" eligible for negotiation in the program.

The first provision identifies a potential qualifying single-source drug using "all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application. "The second provision governs the determination that a generic drug "is marketed," such that an alternative source of the brand drug exists, meaning the brand is no longer a qualifying single-source drug. The guidance provides that a generic drug is marketed "when the totality of the circumstances ... reveals that the manufacturer of that drug or product is engaging in bona fide marketing of that drug or product."

In August 2023, pursuant to the DPNP, CMS selected 10 drugs for negotiation for the initial price period, scheduled to begin Jan. 1, 2026. All the manufacturers whose drugs were selected brought constitutional challenges to the DPNP in federal district courts in the Second and Third Circuits, alleging claims based on the First Amendment, Fifth Amendment due process, the Eighth Amendment, the APA, and the nondelegation doctrine. Each of these challenges was rejected in their respective district and appellate courts, and the Supreme Court declined certiorari on May 18.

Three themes emerged from the decisions of the Second and Third Circuit courts:

(1) Pharmaceutical manufacturers have no constitutionally protected property interest in selling to Medicare at their preferred prices (Fifth Amendment).

(2) Participation in Medicare and Medicaid is voluntary, so manufacturers are not compelled to agree to negotiated prices pursuant to the DPNP (First Amendment).

(3) The penalties imposed on manufacturers who fail to comply with the DPNP are not unconstitutionally excessive (Eighth Amendment).

Three additional challenges to the DPNP remain pending in the Fifth and D.C. Circuits.

The challenge brought by Pharmaceutical Research and Manufacturers of America in the Fifth Circuit may meet a more promising fate than those in the Second and Third Circuits. There, similar to the other unsuccessful challenges to the DPNP in the Second and Third Circuits,

PhRMA and two other pharmaceutical industry organizations alleged violations of the nondelegation doctrine, Fifth Amendment due process, and the Eighth Amendment.

PhRMA specifically argued that Congress, through the IRA, did not supply sufficient guidance to the U.S. Department of Health and Human Services and CMS to implement the DPNP, the DPNP's pricing restrictions constitute an uncompensated taking of pharmaceutical manufacturers' property interests, and the excise taxes imposed for noncompliance with the DPNP are unconstitutionally excessive. Related to the Eighth Amendment claims, PhRMA illustrated the magnitude of the excise tax in their opening brief on appeal to the Fifth Circuit: "The tax ... starts at nearly double the manufacturer's total daily U.S. revenue for the drug [subject to the DPNP], then skyrockets to 19 times that revenue."

The U.S. District Court for the Western District of Texas initially granted summary judgment in favor of the government, finding that the IRA supplied adequate guidance to HHS and CMS to develop the DPNP, and that plaintiffs had no property interest protected by the Fifth Amendment. Additionally, because the Tax Anti-Injunction Act imposes a statutory requirement that potential challengers of a federal tax have standing only if they first pay the tax at issue and then sue for a refund, plaintiffs were barred from bringing an Eighth Amendment claim related to the DPNP's excise tax as they had not first incurred and then paid the tax.

PhRMA appealed the decision to the Fifth Circuit. At oral argument, the Fifth Circuit appeared skeptical of the idea that the TAIA prevents judicial review of the DPNP's excise tax for noncompliance.

Specifically, Judge Cory Wilson questioned the feasibility of applying the TAIA to the excise tax given the magnitude of the tax. Judge Wilson commented, "The district court said, 'no problem, the Anti-Injunction Act, they can pay the tax and then then challenge it'... it seems completely infeasible to do that with regard to this tax, which maybe makes it different than any other tax that's ever been dealt with." In response, counsel for the government noted the lack of precedent holding that TAIA requirements could be avoided by claims that the challenged tax is "too high" to pay and then sue for a refund.

By contrast, the courts in the pending D.C. Circuit cases appear likely to uphold the constitutionality of the DPNP. Merck awaits a decision in the U.S. District Court for the District of Columbia as to its claims that the DPNP violates the First and Fifth Amendments, and Teva awaits decision on appeal to the D.C. Circuit on a finding that the DPNP does not violate the APA or Fifth Amendment.

At oral argument in both cases, the courts noted—as have judges in other jurisdictions—the voluntary nature of participation in Medicare. The D.C. courts appeared skeptical that Congress did not provide sufficient guidance to HHS and CMS in the IRA or that pharmaceutical manufacturers have a property interest in charging preferred prices for their pharmaceutical products.

In any event, Judge Wilson's comments in the PhRMA case make the upcoming decision out of the Fifth Circuit "one to watch" for pharmaceutical manufacturers and their stakeholders. A Fifth Circuit finding that the TAIA does not apply to challenges to the DPNP's excise tax would create a circuit split on the issue, perhaps encouraging the Supreme Court to opine on the constitutionality of the DPNP's greatest source of negotiation leverage—the excise tax.

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Amy N. Vegari is a partner in Patterson Belknap Webb & Tyler's litigation department, where she represents pharmaceutical and health care clients in a range of complex commercial litigations, with a special focus on antitrust law.

Sarah E. Brand is an associate in the firm's litigation department.
