

CAPITOL STREET

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Appellate Court Gives PhRMA's IRA Argument A Chance

NVS & MRK Decisions Forthcoming

Relevant Companies



»» Our Take & Next Up

The Fifth Circuit appeals court reversed and remanded a PhRMA district court decision, marking the first industry "win" in IRA litigation. The decision released Friday Sept 20 ([here](#)) reversed a lower court decision noting that the National Infusion Center Association (NICA) has standing to sue because it is challenging the *Inflation Reduction Act* and not the *Medicare Act*, which would have required claims to be channeled through HHS. The case is now remanded to the district court and PhRMA will have an opportunity to have its case judged on the arguments. However, the appeals court also noted that NICA did *not* prove its standing to bring its nondelegation and excessive fines claims which may alter the types of arguments presented by PhRMA. PhRMA may focus on the Fifth Amendment violation as a result. **TIMELINES GOING FORWARD:** (1) We expect the district court to reconsider the case with a potential decision in early 2025. In other negotiation proceedings, we expect (2) district court decisions any day now on the **MRK** (pending in DC) and **NVS** (pending in NJ). (3) Oral arguments are scheduled for October 28 for **JNJ, BMY, AZN's** appeal cases. Remember (4) final 2027 negotiation program guidance is expected this Fall, which may provide additional implementation details including potentially some lessons learned from 2026 negotiation process. Our analysis on the proposed 2027 guidance is [here](#).

»» Key Points

The decision states that NICA has associational standing based on economic injury and procedural injury. The courts ruled that NICA has sufficient standing due to the economic harm their members face and the lack of due process that denied NICA the chance to protect their interests.

- The decision noted that NICA showed sufficient standing as at least one of its members' (**BioTek**) drug Stelara will be subject to negotiations, that will lower the price for that drug, and that the lower price will lead to lower revenue for the members that administers the drug. NICA was able to successfully argue future harm from inclusion of Part B drugs as providers reimbursement will shrink from a decrease in market price based on reimbursement tied to 106% of the cost of the drugs.
- The court also stated that NICA illustrated procedural injury as the association was denied the chance to ask implementation questions & unable to challenge key determinations through CMS's implementation process.

- Circuit Judge Irma Carrillo Ramirez, who wrote an opinion concurring in part and dissenting in part, echoed the district court in stating “even if NICA had standing, its claims cannot be disentangled from the Medicare Act” and stating NICA had no standing to bring the case.

NICA does not have to channel its claim through HHS because it is challenging the *Inflation Reduction Act*, not *Medicare Act*. As a reminder, claims that relate to the Medicare Act must be “channeled” through the relevant agency and the agency must make a final determination before they can be challenged in federal court. The Fifth Circuit ruled that NICA is challenging a provision of the *Inflation Reduction Act* because it is challenging the Drug Negotiation Program itself, not the negotiated prices that are determined for Medicare reimbursement.

The appeals court asserts that negotiated prices are likely to have a commercial ripple effect. The court agreed with NICA that the “Drug Pricing Program “[sets] rules for the entire ecosystem.”” The decision pointed to potential private market effects of negotiations as a supporting argument that the lawsuit goes beyond Medicare reimbursement.

However, NICA lacks standing to bring its nondelegation and excessive fines claims. The court ruled that while there is a plausible procedural injury for these claims, it is not NICA’s procedural injury and so does not provide standing for NICA. The arguments that are allowed to be presented may be altered to better fit what NICA, PhRMA, and Global Colon Cancer Association is allowed to argue. As a reminder, PhRMA argued that the Drug Pricing Program violates the nondelegation doctrine, the excessive fines clause of the Eighth Amendment, and the due process clause of the Fifth Amendment.

Litigation scorecard is provided below.

- NICA, PhRMA, GCCA (Dismissed in TX, 5th Circuit reversed and remanded) – 5th & 8th Amendment violation, nondelegation violation
 - MRK (Pending in DC district court) – 1st & 5th Amendment violation
 - NVS (Pending in NJ district court) - 1st & 5th & 8th Amendment violation, separation of powers and APA violation
 - NVO (ruled in the government’s favor in NJ, appealed to the 3rd Circuit) – nondelegation/separation of powers, 1st & 5th Amendment, Unconstitutional conditions, statutory challenge (10 product limit)
 - Opening brief due from NVO by October 15
 - Boehringer Ingelheim (ruled in the government’s favor in CT, appealed to the 2nd Circuit) – 1st & 5th & 8th Amendment violation, APA violation
 - Opening brief due from BI by October 25
 - JNJ & BMY (ruled in the government’s favor in NJ, appealed to the 3rd Circuit) – 1st & 5th Amendment violation, unconstitutional conditions doctrine violation
 - Oral argument scheduled for October 28 in Philadelphia
 - AZN (ruled in the government’s favor in DE, appealed to the 3rd Circuit) – APA, Orphan Drug Act, and 5th Amendment violation
 - Oral argument scheduled for October 28 in Philadelphia
 - Dayton Chamber of Commerce (Dismissed in OH) - 1st & 5th & 8th Amendment violation, separation of powers violation
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