

February 13, 2024

## PhRMA Negotiation Lawsuit Dismissed in TX Court

Next Up: MRK, JNJ/BMY Lawsuits; Claims Likely Introduced in Different Ct

Relevant Companies



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### »» Our Take & Next Up

**One notched legal win for the Biden administration.** The decision may signal the federal courts' approach to the IRA drug negotiation program which may hurt manufacturers and stakeholders in their case against HHS. Yesterday, Judge David A. Ezra (appointed by Pres Ronald Reagan) dismissed the case brought by the National Infusion Center Association (NICA), Global Colon Cancer Association (GCCA), and PhRMA due to the Medicare Act's jurisdictional bar over judicial review [here](#). With NICA losing subject matter jurisdiction, the case was dismissed as neither GCCA nor PhRMA reside in the Western District of Texas. The case can be filed in another court, so it's not game over for PhRMA but similar HHS claims hurdles could exist. We now look to (1) [Merck](#) and (2) [Johnson & Johnson](#) decisions in the next few days or weeks. We provide more detail below.

### »» Key Points

**The infusion centers (NICA) failed to show an exception to the Medicare Act's jurisdictional bar.** A claim under the Medicare Act is barred from judicial review until after the Secretary of Health and Human Services renders a "final decision" on the claim. The judge noted that claims "arise under" the Medicare Act, even when the claim is for reimbursement or is a constitutional challenge and the claim did not qualify for a 'complete preclusion of judicial review'.

**The case could be initiated in another state, but the same issue may arise: PhRMA/NICA haven't presented claims to HHS first.** With NICA out of the case, the case was dismissed as neither GCCA nor PhRMA resides in Texas. The judge also pointed out that, while the case could be transferred to a different court, the same jurisdiction issue likely exists for PhRMA and GCCA, as neither party has presented its claims to HHS for a decision first.

**Constitutional violations alleged in the case are below.**

- IRA's drug negotiation program violated the non-delegation principle as Congress has granted broad, unconstrained authority to CMS to set prices in Medicare without judicial review.
- It violated the Eighth Amendment's excessive fines clause as the excise tax functions as a penalty which over-punishes pharmaceutical companies that do not agree to CMS's price.

- The program violates the Fifth Amendment’s due process clause by exempting key decisions from public input and “insulating them from administrative or judicial review”.

**There are 7 other ongoing lawsuits against drug negotiations with next court decisions likely in 1Q 2023.** BMS/JNJ & MRK lawsuits have wrapped up their briefing schedule and are likely next to see a decision. Ongoing cases include MRK’s [lawsuit](#) filed in the District Court for DC, BMY’s [lawsuit](#) combined with JNJ’s [lawsuit](#) in New Jersey, the Chamber of Commerce’s [lawsuit](#) filed in Ohio, AstraZeneca’s [lawsuit](#) filed in Delaware, Boehringer Ingelheim’s [lawsuit](#) filed in Massachusetts, Novartis’ [lawsuit](#) filed in New Jersey, and Novo Nordisk’s [lawsuit](#) filed in New Jersey.

**Next up for negotiations, selected manufacturers must accept or propose a counteroffer to CMS by the beginning of March.** Other key dates include:

- August 1, 2024 – The negotiation period for 2026 ends (three meetings)
- September 1, 2024 – Maximum fair prices publication due date
- February 1, 2025 – CMS to announce the list of 15 drugs (Part D) subject to negotiations in 2027
- March 1, 2025 – Deadline for CMS to publish explanation of the maximum fair prices
- January 1, 2026 – Maximum fair prices are effective for selected drugs

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