

CAPITOL STREET

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Capitol Street Drug Negotiation (IRA) Tracker

»» Our Take & Next Up

We believe that the Courts are not going to strike down IRA-passed Medicare drug negotiation at this time: three pharma companies have oral arguments set for next month (Boehringer Ingelheim, NVS & NVO) as other decisions are due "any day now" (MRK, BMY, JNJ, AZN). Medicare reimbursement has long been considered a voluntary exercise by the Courts who do not want to face the task of potentially setting Medicare reimbursement rates. Additionally, the Trump administration has signaled support for the negotiation program ([here](#)), choosing to defend the IRA in the lawsuit from Novartis. However, the APA violations alleged and the lack of CMS rulemaking may be criticized and result in the agency being required to be transparent through the maximum fair price (MFP) setting process.

Next up & one case to watch: Oral arguments for BI, NVO and NVS are scheduled for April 4 and April 8 respectively. A slew of decisions (MRK, BMY, JNJ, AZN) are also expected to be released "any day now." Conflicting appeals court decisions are expected to eventually reach the Supreme Court. As 2026 approaches, we could see more appeals cases pass the hurdle of "standing" as trade organizations and individual manufacturers have previously struggled at the district court level to have their cases judged on the merit of their arguments. **PhRMA's lawsuit (5th Circuit)** was remanded back to the western district of Texas. They are likely confident in their argument against the IRA now that the case can be reviewed on its merits. See our analysis on the PhRMA lawsuit [here](#) and appellate decision [here](#).

We believe all manufacturers have likely agreed to participate in 2027 negotiations. Publicly, at least eight pharma companies (AMGN, AZN, Astellas, Boehringer Ingelheim, BMY, GSK, TEVA, MRK), [agreed](#) to take part in 2027 negotiations, which covers 10 of the 15 drugs selected by CMS. CMS is scheduled to submit its initial offers by June 1, and negotiations will take place over the following months. Negotiated prices will be published by the end of November this year, going into effect starting January 2027. Our take on the fifteen 2027 Part D medicines for negotiation are [here](#).

»» Key Points

Litigation Scorecard

	Link	Next Up	1st Amdt	5th Amdt	8th Amdt	Separation of Powers	APA violation	10 Drug Limit	Unconstitutional Conditions
Merck (MRK)	DC District Court case here	Waiting on a decision any day now	X	X					
Bristol Myers Squibb (BMY)	3rd Circuit case here	Waiting on a decision any day now	X	X					X
J&J (JNJ)	3rd Circuit case here	Waiting on a decision any day now	X	X					X
AstraZeneca	3rd Circuit case here	Waiting on a decision any day now		X			X		
Novo Nordisk	3rd Circuit case here	Oral Arguments 4/8/25	X	X		X	X	X	
Novartis	3rd Circuit case here	Oral Arguments 4/8/25	X	X	X				X
Boehringer Ingelheim	2nd Circuit case here	Briefing Ongoing	X	X		X	X		X
Chamber of Commerce	6th Circuit case here	Briefing Ongoing	X	X	X	X			
PhRMA, NICA, GCCA	5th Circuit case here	Govt's Cross Motion for Summary Judgement Due 4/21/25		X	X	X	X		
Teva	Filed in DC here	Scheduling Conference 3/4/25		X			X		

Notes

- **1st Amendment, compelled speech.** Companies will be forced to communicate that they have “agreed” and endorse HHS’s “fair price” even when they do not agree with this characterization
- **5th Amendment, takings clause.** The Drug Negotiation program denies manufacturers their protected property interest without constitutional adequate procedures.
- **5th Amendment, due process.** No due process for negotiation - price controls with no protection
- **8th Amendment, excessive fines.** Negotiations institute "fines two-and-a-half to 25 times greater than the statutory penalty for criminal tax fraud"
- **Separation of Powers.** Congress has impermissibly delegated sweeping authority to a federal agency to implement price controls without providing a clear standard to guide the agency’s discretion or including other protections necessary
- **APA violation.** CMS’s poor implementation violated the APA bc they didn’t take public comment on important parts of the guidance. CMS definition of a Qualifying Single Source drug lumps different products together under different NDAs, Bona Fide marketing violation
- **Orphan Drug Act.** IRA undermines the Orphan Drug Act by reducing the market incentives for new drugs

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