

# CAPITOL STREET

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September 15, 2023

## IRA Oral Arguments Provide Some Clues

Our Odds of Preliminary Injunction Granted Are 30%

Relevant Companies



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Today, the district court of the southern district of Ohio held their oral arguments for the motions filed in the Dayton Area Chamber of Commerce et al. v. Becerra case. There are 2 motions under consideration: (1) Chamber's motion for a preliminary injunction and (2) the government's motion to dismiss the case due to lack of standing.

### »» Our Take & Next Up

**We do not believe the law will be halted ahead of October 1 by Judge Newman (Trump appointee); we still hover around 30% odds of a preliminary injunction.** The judge will issue a decision by Oct 1 – the federal government asked for the case to be tossed while the Chamber is asking for an injunction to halt the law immediately. We believe that the Chamber made a solid argument regarding coercion. Coercion will come up in other lawsuits (see our 8 case roundup below). We also believe that AbbVie/Pharmacoclics likely have standing versus the Chamber (gov't argument). It is likely hard to prove that harm has already taken place, as the Chamber asserts irreparable cost & harm. See main arguments below.

### »» Key Points

The oral arguments today were heard by Judge Michael J. Newman, who didn't ask a single question today in the 2+ hour session held via conference call. Newman ([here](#)) is a Trump appointee who previously served in the Dayton seat of court as a Magistrate Judge. He remained largely silent during arguments and did not engage in questioning counsels. His practice areas in the past include labor and employment, business litigation, ERISA litigation, and appellate litigation.

**We put the odds of a preliminary injunction being granted at 30%.** There is little urgency for a judge to stop implementation at this time. The District Court is expected to release a decision within the next 2 weeks as the request asks for an injunction by

October 1, or the due date for companies to engage in a negotiation with CMS. While a single judge can enter a nationwide, preliminary injunction to block the program, we think it's less likely to occur at this stage. The standard of evidence required to prove "irreparable harm" for a preliminary injunction is high and Chamber must prove it before 'the negotiation process' even begins. Additionally, prices do not go into effect until 2026.

**The OH Chamber of Commerce asked for preliminary injunctive relief**, based on their likelihood of succeeding on the due process violation and the irreparable harm faced by AbbVie (ABBV), a member.

1. The Chamber argued that the program has the "trappings of a negotiation" as there is a lack of procedural protection under the IRA for a fair price (*Michigan Bell Tel. Co. v. Engler*) and the excise tax and advanced requirement to agree to negotiations by Oct. 1 make negotiations coercive by the program's nature.
2. The Chamber also noted that manufacturers are reliant on a nonbinding negotiation process. Manufacturers that participate in the negotiation process, or, if they choose to withdraw, will be reliant on guidance from CMS who also have unilateral power to change agreements.

**The federal government countered by saying that Medicare (and negotiations) are voluntary, so companies can walk away.** They noted that in the past Courts have ruled that Medicare is a voluntary program regardless of the changes to program (*Baptist Hosp. E. v. Sec'y of HHS*) and Courts have ruled before that financial loss doesn't always equate to deprivation of property in Medicare. The administration ended by cautioning the judge that not every challenge to government actions raises big issues and pointed to prior Court cases regarding nursing home Medicare reimbursement.

**The Biden administration asked to dismiss the case entirely arguing Chamber's lack of standing (it's Pharmacyclics, not ABBV, and not the Chamber) to bring the lawsuit and because individual manufacturers have a legal recourse path.** The administration argued that the Chamber lacked standing as AbbVie (the only identified member) is not 'the manufacturer' that will negotiate with CMS. The administration focused on the fact that Pharmacyclics (a wholly owned subsidiary of AbbVie) is the actual manufacturer of Imbruvica and Pharmacyclics was not a member of Dayton Area Chamber of Commerce at the time of filing.

**The administration also asserted that financial harm remains unclear due to rebate exemptions provided to negotiated drugs, and final negotiated prices may be higher than under current system (w/ rebates).** Chamber countered that CMS treats "all members of corporate family as joined at the hip" (all in or all out) and AbbVie has faced real injury as AbbVie has spent funds and lost manpower to prepare for negotiations for Pharmacyclics. The Chamber stated that AbbVie has standing from this injury and as a result, the Chamber has standing to sue. The organization also noted that the potential harm is material as any statutory ceiling for Imbruvica will result in a loss.

**Currently, there are eight lawsuits that are proceeding through multiple District Courts.** They include MRK's [lawsuit](#) filed in the District Court for DC, BMY's [lawsuit](#) filed in a District Court for New Jersey, JNJ's [lawsuit](#) filed in a District Court for New Jersey, the Chamber of Commerce's [lawsuit](#) filed in a District Court for Ohio, Boehringer Ingelheim's [lawsuit](#) filed in a District Court in Massachusetts, include AstraZeneca's [lawsuit](#) filed in Delaware, and PhRMA's [lawsuit](#) filed in District Court for the Western District of Texas. Since the release of CMS's top 10 list, the newest filing is Novartis' [lawsuit](#) filed in New Jersey.

**Following the release of the top 10 drugs selected, Astellas has withdrawn its lawsuit in Illinois.** The company filed its lawsuit ahead of the announcement this summer due to expectations that Xtandi (prostate drug) would be included. Astellas was the only company to file a lawsuit that was ultimately left out of the program. Despite the relative predictability of the 2026 list, the lawsuit withdrawal is an example of the uncertainty that remains around selection.

**Why do cancer drugs (largely) not appear on the list?** In the top 10 release August 28, CMS included gross expenditures but also considered # of total prescriptions. The agency is trying to make an argument for the wide impact on beneficiaries and

highlight the importance of the program in lowering costs. It is uncertain what additional factors CMS will weigh in the subsequent lists -- 2027, 2028 – and may release new guidance for the process in subsequent years.

**As a reminder, October 1 is the deadline for manufacturers to agree to the negotiation process for 2026.** Then companies must submit any relevant data for setting the maximum fair price by October 2, 2023. Additional dates can be found in the negotiation timeline below.

- Negotiation period: October 2, 2023, to August 1, 2024.
- Written initial offer deadline: February 1, 2024
- Negotiated Price publication date: September 1, 2024
- Presidential election: November 5, 2024
- Deadline for publication of the 2027 list: February 1, 2025.
- Deadline for explanation of the negotiated price: March 1, 2025.
- Negotiated price effective date: January 1, 2026.

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