

Mintz IRA Update — Legal Challenges to the Medicare Drug Price Negotiation Program Continue

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The IRA's Medicare Drug Price Negotiation Program (the "Negotiation Program" or "Program"), which aims to lower drug prices by enabling the federal government to negotiate prices for some of the costliest Medicare Part D drugs, has been the source of **controversy** and subject to several **legal challenges**. As we previously **covered**, seven manufacturers of drugs selected for the Program ("Selected Drugs") and two trade associations brought lawsuits challenging the Negotiation Program between June and September 2023. With the exception of Enbrel, which is manufactured by Amgen, a lawsuit has been filed for each of the Selected Drugs either directly by a manufacturer or by a trade association representing a manufacturer.

Here we provide a summary of noteworthy developments since our last Update. Note that despite the ongoing litigation, each of the manufacturers of the 10 Selected Drugs entered into price negotiation agreements with CMS by the October 1, 2023 deadline, which we previously covered in more detail.

Texas Suit Brought by PhRMA and Other Trade Associations Dismissed on Procedural Grounds

On February 12, 2024, a federal judge in Texas **granted** the government's motion to dismiss a lawsuit brought by Pharmaceutical Research and Manufacturers of America (PhRMA), the National Infusion Center Association (NICA), and the Global Colon Cancer Association (GCCA) on the grounds of lack of subject matter jurisdiction and improper venue. The court agreed with the government that NICA — the only party to the suit residing in Texas — did not satisfy the jurisdictional prerequisites of the Medicare Act, which divests courts of federal question jurisdiction over "any claim arising under" the Medicare Act unless the claim has first been presented to the agency and all administrative remedies have been exhausted. Following its dismissal of NICA's claims for lack of subject matter jurisdiction, the court ruled that venue (i.e., Texas federal court) was no longer proper for the claims brought by PhRMA or GCCA. The case was dismissed without prejudice, meaning the plaintiffs can bring another lawsuit after satisfying the administrative exhaustion requirements, or PhRMA and GCCA could bring suit in their home districts. NICA may also appeal the court's decision to the Fifth Circuit, though such an appeal would likely take a few months and still be solely focused on procedural, not substantive issues.

Negotiation Program Survives Motion for Preliminary Injunction

On September 29, 2023, a federal judge allowed the implementation of the Negotiation Program to proceed, rejecting a **Motion for Preliminary Injunction** against the Program brought by the Dayton Area Chamber of Commerce and the US Chambers of Commerce, among other groups. The federal judge **ruled** that the plaintiffs "have not shown a strong likelihood of success on the merits of their due process claim." The plaintiffs **argued** that the Negotiation Program's price-control regime runs afoul of due process principles because it lacks a mechanism to ensure that drug manufacturers are not subject to arbitrary and confiscatory prices. However, the judge rejected the plaintiffs' argument on the grounds that manufacturers' participation in the Negotiation Program is voluntary, and drug manufacturers can opt out of it. This decision may signal how judges in the other cases brought against the Negotiation Program will rule on similar issues.

Novo Nordisk Files Lawsuit, Makes New APA Violation Claim

On September 29, 2023, Novo Nordisk — the manufacturer of diabetes drugs that CMS selected for negotiations — filed another **lawsuit** against the Negotiation Program. In addition to raising many of the

same arguments the other challengers have made, Novo Nordisk is also alleging an APA procedural violation based on CMS's failure to engage in notice-and-comment rulemaking for the price negotiation agreement. The government filed its [initial response](#) to this new claim on January 26, 2023.

Expected Timeline of Briefings and Decisions

Decisions in the nine cases challenging the Negotiation Program will likely be made by spring 2024:

- The cross-motions for summary judgment in the Merck case concluded briefings on November 29, 2023.
- The remaining cases' briefing schedules are set to conclude by March 22, 2024.
- While decisions can be expected anytime after the briefings conclude, the court in AstraZeneca's case has [indicated](#) that it will aim to issue a decision by March 1, 2024 — one day before the manufacturers will have to respond to CMS's initial drug price offer. Oral arguments for this case occurred in late January 2024, during which the district judge seemed to express skepticism towards AstraZeneca's Taking's claims.

Selected Drug Manufacturers All Agree to Negotiate with CMS; Negotiation Program Proceeds

Despite the ongoing litigation, all nine drug manufacturers of the 10 Selected Drugs agreed to participate in price negotiations with CMS, according to a CMS [announcement](#) on October 3, 2023. The manufacturers also submitted manufacturer-specific drug data to CMS in early October.

According to [CMS](#), the agency will rely on submitted data, meetings with the drug manufacturers, and listening sessions held in October and November to make its initial price offers. Following the initial offers, the drug manufacturers will have 30 days to respond, either by accepting the initial offer or proposing a counteroffer. The negotiation period is set to conclude by August 1, 2024, and the negotiated maximum fair prices will go into effect on January 1, 2026.

AARP and Advocacy Groups Show Support the Negotiation Program

AARP, the American Public Health Association (APHA), and various other advocacy groups, along with policy experts, have submitted amicus briefs in support of the Negotiation Program in several of the cases. In its November [amicus brief](#) against AstraZeneca's efforts to stop the Program, AARP argued that the Negotiation Program "will help millions of older people access affordable medication and protect the financial security of Medicare." The Negotiation Program, according to an October [amicus brief](#) filed by APHA, is a "vital first step in ensuring the health of Americans and the Medicare program."

Authors



Xavier G. Hardy, Associate

Xavier represents clients in the health care and life sciences fields on health care regulatory and fraud and abuse matters. He also handles Medicare and Medicaid reimbursement issues in transactions and business arrangements.



Matthew Tikhonovsky

Matthew is a Mintz Senior Project Analyst based in Washington, DC.

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