

07 Mar 2024 | News

IRA Litigation: NJ Judge Looks For Own Path In Evaluating Medicare Price Negotiation Program

by [Brenda Sandburg](#)

During oral argument in four cases challenging the IRA, Judge Zahid Quraishi suggested he may find that Medicare participation is voluntary but takings claim would still need to be considered. On question of whether the program is hurting innovation, Quraishi seemed skeptical.

New Jersey District Judge Zahid Quraishi oversaw a lively oral argument in four cases challenging the Medicare drug price negotiation program. He did not indicate how he might rule but suggested that he may find that participation in Medicare is voluntary, which could undercut industry's constitutional claims. He also questioned industry's assertions that the program is harming innovation.

The 7 March oral argument was delayed as the courthouse in Trenton was closed for more than an hour after fire trucks and a hazardous material response team arrived to investigate what a guard said was a suspicious package. Teams of lawyers waited outside a building across the street. A courthouse worker walked by and asked what was going on, commenting that the courthouse is never this busy.

The mood was somewhat cheerful as a long line of lawyers, reporters and others went through security. There were 11 attorneys at the table for the plaintiffs – [Bristol Myers Squibb Company](#), [Janssen Pharmaceuticals Inc.](#), [Novartis AG](#), and [Novo Nordisk A/S](#) – and three attorneys from the US Department of Justice representing the Department of Health and Human Services. (See *sidebar for chart of counsel in the cases*).

About 50 other people were in the courtroom. At the end of the hearing, Judge Quraishi noted that others listened in from an overflow room.

Quraishi asked several questions and elicited laughter with light-hearted comments. In one instance he asked what, if anything, he should take from the judge's decision in AstraZeneca's case against the government. Novo's counsel Ashley Parrish, a partner at King & Spalding, replied, "not too much."

In that case, Delaware District Judge Colm Conolly granted the government's motion for summary judgement. He rejected the company's constitutional claims and found that because AstraZeneca's participation in Medicare is not involuntary, the company does not have a protected property interest in selling drugs to the government at prices the government will not agree to pay. (Also see "[Second Judge Rejects Constitutional Challenges To Medicare Price Negotiation Program](#)" - Pink Sheet, 1 Mar, 2024.)

The government contends that companies can withdraw from participating in Medicare and Medicaid if they do not agree to participate in the drug negotiation program. But companies argue that participation is not voluntary as they would have to stop selling all of their drugs to these government programs.

Judge Quraishi said the voluntariness issue seems to be a threshold issue. "Even if I find the program is voluntary that is not the end of your argument?" he asked Samir Deger-Sen, a partner at Latham & Watkins representing Novartis.

Deger-Sen replied no, "avoidance is not voluntary." He argued that the program is a physical taking of property and it doesn't matter if you can avoid the penalty for not participating in the program by exiting the market.

Judge Quraishi later raised the issue again, saying "regardless if I find the program is voluntary, I would still have to do analyses of the taking claim."

Need More Data To Argue Harm To Innovation

Janssen's counsel Kevin King, a partner at Covington & Burling, said the Supreme Court has found that a program is not voluntary if it has coercion. The excise tax imposed for not participating in the program is "so crippling no company could ever incur it," he said. He noted that the companies together would have to withdraw more than 120 drugs from Medicare and it would cost "an arm and leg if they don't."

"Folks would say pharmaceutical companies could give up an arm, they have a lot of

Who's Who In The IRA Court Drama

By **Brenda Sandburg**

07 Mar 2024

Pink Sheet offers a graphical guide to the lawyers behind the briefs and at the podiums for the big showdown in Trenton.

[Read the full article here](#)

appendages,” Quraishi replied.

Quraishi noted that companies say they won’t be able to fund R&D because of the program. But he said he would need more information for them to make that argument, such as what was spent on advertising, executive compensation and stock buyback. If you say the program will harm pharmaceutical companies “you have to give me more than ‘I said it is so,’” he stated.

He also asked if there aren’t mechanisms in place, such as patents and market exclusivity, to address the high cost of drug development.

Quraishi asked if any company had withdrawn from the Medicare market because of the price negotiation program. Counsel responded that they were not aware of any company doing so.

Brian Netter, deputy assistant attorney general for the federal programs branch, said that those who do not wish to participate in price negotiation have the recourse to stop selling their products to the government. He said none of those involved in litigation against the program have signaled an intent to withdraw.

Quraishi said that could cut against the government if the program is so coercive companies would be forced at gunpoint to execute agreements with the government.

Scoring Political Points

Attorneys also argued claims that the program violates the First Amendment by compelling participants to describe themselves as engaging in a “negotiation” to determine a “maximum fair price.”

Bristol Myers Squibb’s counsel Yaakov Roth, a partner at Jones Day, said that instead of mandating access to a maximum fair price, the government added extra steps of negotiating and then agreeing to provide the price. “Why do it in this circuitous way?” he asked. He said there is public support for a negotiated price but not a top-down approach and the government seized on its approach for political purposes.

Roth noted that the fact sheet the White House issued ahead of the State of the Union address had as its first bullet point that manufacturers of 10 drugs were at the negotiating table hammering out a fair price. In his 7 March address, Biden called for expansion of the program. (Also see "[Biden’s Pharma Plans Keep Industry Fighting On All Fronts](#)" - Pink Sheet, 7 Mar, 2024.)

“By mandating manufacturers to agree, the program is requiring manufacturers to indict themselves on an unfair drug price,” Roth stated.

Parrish made a final argument noting that the price negotiation program had a particular impact

on Novo, which has six insulin products subject to price negotiation because they contain the same active ingredient. He said Congress granted CMS authority to negotiation pricing for 10 drugs and CMS made it 15 by claiming Novo's six were one product.

Pharma Losing So Far

Last August, the Centers for Medicare and Medicaid Services released a list of 10 drugs chosen for the first round of Medicare price negotiation. All of the manufacturers of the selected drugs agreed to participate in the program and negotiate a maximum fair price for their selected products. CMS sent initial offers of a maximum fair price for the drugs and manufacturers were to submit counteroffers to CMS on 2 March.

To date, district courts have issued rulings in three of the nine cases challenging the Medicare drug price negotiation provision of the Inflation Reduction Act.

In addition to AstraZeneca's case, a judge in the US District Court for the Western District of Texas granted the government's motion to dismiss a suit filed by the Pharmaceutical Research and Manufacturers of America and two co-plaintiffs on jurisdictional grounds without addressing the merits. (Also see "[PhRMA's Lawsuit Against Medicare Trips Over 'Administrative Remedy' Standard; Will Others?](#)" - Pink Sheet, 14 Feb, 2024.)

And in the US Chamber of Commerce's case, a judge in the US District Court for the Southern District of Ohio denied its motion for preliminary injunction to halt implementation of the program. He asserted that participation in Medicare was voluntary and that the Chamber had not shown there were no circumstances under which the program would be constitutionally valid under the Fifth Amendment Due Process clause.

The judge also said the plaintiffs had not shown a strong likelihood of success on the merits of their due process claim. (Also see "[IRA Litigation Hurdles Clarified With Ruling In Chamber Of Commerce Suit](#)" - Pink Sheet, 2 Oct, 2023.)

'Educational Opportunity'

In the New Jersey case, Judge Quraishi said he needed to make sure he has subject matter jurisdiction and questioned how the cases before him differ from that in Texas. DOJ attorney Alexander Sverdlov said there is a different rule that applies to reimbursement for providers. He said in the Texas case PhRMA found an association of local providers to be a plaintiff and they had a different statutory framework for compensation.

Judge Quraishi praised the attorneys at the close of the hearing.

"Today there has been absolutely outstanding work from attorneys" on both sides, he said, mentioning the name of each counsel who argued before him. He said this district court is not

known to be generous in offering oral argument as it is often redundant, but he said today's oral argument was informative on complex issues.

"You offered an educational opportunity for attorneys in the room and clerks observing your advocacy," he said.