

Merck Sues U.S. Government Over Medicare Price Negotiation Process

Pharmaceutical company Merck recently filed a [lawsuit](#) against the U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS), claiming that the Inflation Reduction Act's (IRA) Medicare drug price negotiation process violates the U.S. Constitution. According to the lawsuit, the act's negotiation process allows the government to unilaterally impose its preferred price. The company is asking the U.S. District Court for the District of Columbia for an injunction to stop the negotiation rules from going into effect within the coming months. Merck is the first major drugmaker to challenge the law.

“Because this statute impairs our core purpose of engaging in innovative research that saves and improves lives, Merck intends to litigate this matter all the way to the U.S. Supreme Court if necessary.”

- Merck spokesperson Robert Josephson

The lawsuit centers around the IRA's negotiation process, which permits the federal health secretary to negotiate the prices of certain expensive drugs annually for Medicare. While negotiations are

scheduled to begin in 2026 for a maximum of 10 prescription drugs covered by Medicare, the CMS is planning to release a list of the first 10 drugs for negotiations on Sept. 1, 2023. Merck's blood sugar medication Januvia is likely to be among the 10 medications selected, with its cancer drug Keytruda and diabetes treatment Janumet likely to be selected in future negotiations.

Merck argues that the law's negotiation process and required rebates if drug prices increase beyond the rate of inflation violate the Fifth Amendment's takings clause, which requires the federal government to provide “just compensation” for any property taken for public use. Merck also claims that the negotiation process infringes on the company's freedom of speech because the IRA forces companies to sign agreements stating that prices are fair.

What's Next

It's unclear whether Merck has standing to sue since the CMS hasn't yet identified the drugs that will be subject to the first round of negotiations. However, due to the lawsuit, the timing of Medicare drug negotiations may be uncertain.

While this lawsuit could have large ramifications for the prescription drug industry and drug prices, it's a developing story and employers are encouraged to monitor it closely.

We will keep you apprised of any notable updates. Contact Creative Benefits, Inc. for more health care resources.