

## US pharmaceutical companies sue to halt cuts in drug prices

Medicare will soon be able to negotiate some drug prices to reduce costs for patients and taxpayers. Susan Jaffe reports from Washington, DC.



The first set of ten drugs subject to price negotiations by the US Medicare programme will be unveiled on Sept 1, 2023, but some pharmaceutical companies and their allies are not waiting to find out which products will be on the list. So far, four manufacturers and two trade associations are suing to stop the process before it begins.

Since the US Congress added a prescription drug benefit in 2003 to Medicare, the health-insurance programme for 66 million older or disabled adults has been forbidden to negotiate prices. Instead, pharmacy benefit managers working for insurance companies seek discounted prices from drug companies, an arrangement largely shielded from the public. “The drug industry got truly a sweetheart deal where—unlike every other seller of goods and services to the American Government—it alone has been allowed for almost 20 years to literally dictate the prices of drugs to Medicare”, said David Mitchell, President of Patients for Affordable Drugs. “And the result is that the people in the United States are paying about three and a half times what other wealthy nations pay for the same brand-name drugs.”

However, in a remarkable loss for the industry in 2022, it failed to persuade Congress to remove the drug-negotiation provisions of the Inflation Reduction Act, a key legislative victory for President Joe Biden that passed without a single Republican vote. These provisions authorise Medicare to negotiate prices for 60 medicines by 2029 that are high cost and meet other criteria, with additional drugs to be added over time. The negotiated prices for the first ten drugs will take effect in 2026 and will include only those self-administered outpatient drugs covered under Medicare’s Part D.

The programme is expected to save the federal government as much as \$102 billion in its first decade, according to the Congressional Budget Office. A study by KFF found that, in 2021, the ten bestselling drugs cost \$48 billion—more than double the cost in 2018—based on sales alone and excluding intravenous and other doctor-administered medications that are covered by Medicare’s Part B. Of the more than 3500 prescription drugs covered by part D, these ten account for 22% of total gross spending.

The companies that are suing the Biden Administration are Janssen Pharmaceuticals, Merck, Astellas Pharma, and Bristol Myers Squibb, as well as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the US Chamber of Commerce. In its lawsuit, Merck described the negotiation process created by the federal law as “tantamount to extortion” and PhRMA’s lawsuit called it “price setting”. According to Janssen’s lawsuit, this “coercive scheme... supplants the free-market system with punitive price controls, granting a government agency nearly unlimited authority to set drug prices at arbitrary amounts untethered to the value of those medications to patients”. The US Chamber of Commerce, a trade association representing more than 3000 businesses, cited the dangers of government interference in the marketplace.

“If the government can impose price controls in this fashion on drug companies, then the government could do the same thing to any sector of our free enterprise system”, said Jennifer Dickey, Deputy Chief Counsel of the US Chamber of Commerce Litigation Center. Lower prices could force drug manufacturers to

cut research and development, she said, which would adversely affect downstream suppliers and other companies that work with drug manufacturers.

“The Biden–Harris Administration isn’t letting anything get in our way of delivering lower drug costs for Americans”, Secretary of Health and Human Services Xavier Becerra responded in a June, 2023 statement. “Pharmaceutical companies have made record profits for decades. Now they’re lining up to block this Administration’s work to negotiate for better drug prices for our families. We won’t be deterred.”

The companies claim that the programme is unconstitutional because it violates their 14th Amendment right to due process and the 1st Amendment freedom of speech guarantee by requiring them to accept a “maximum fair price” they say will not be fair. They also claim that the programme allows the government to seize their property—prescription drugs—without sufficient reimbursement. The 5th Amendment to the US Constitution prohibits the government from taking private property for public use without adequate compensation.

For the KFF analysis see <https://www.kff.org/medicare/issue-brief/a-small-number-of-drugs-account-for-a-large-share-of-medicare-part-d-spending/>



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Janssen expects that its blood thinner, Xarelto, will be among the first ten drugs that are subject to price negotiation and said that the company would never voluntarily agree to the terms the government will set. In 2021, Medicare's gross spending for the drug was \$5.2 billion, a 53% increase since 2018, according to the KFF analysis. Ozempic, a Novo Nordisk drug for diabetes, is also expected to be one of the first ten drugs. Medicare's gross spending for the drug was \$2.6 billion in 2021, 46 times more than in 2018, according to KFF. Eliquis, Bristol Myers Squibb's blood thinner, is also likely to be on the list. Medicare's gross spending for the drug was \$12.6 billion in 2021, an increase of 152% since 2018, the KFF analysis found.

The pharmaceutical industry's arguments "cut against substantial precedents", said Zachary Baron, Associate Director of the Health Policy and the Law Initiative at the O'Neill Institute for National and Global Health Law at Georgetown University Law Center. Price negotiations are already an intricate part of the government's health-care system. "Federal health programmes purchase goods and services from doctors, hospitals, health insurers, and drug companies and many accept payments that are less than the reimbursement available from the commercial markets", he said. The 2003 prohibition against negotiating drug prices "has always been an aberration in the Medicare program".

Courts have ruled that government price regulation "does not constitute a taking of a property when the regulated group is not required to participate", he continued. "The government isn't marching into Merck or Bristol Myers factories and just taking the drugs away from them."

Even when the Medicare drug-price negotiation programme is fully operational, pharmaceutical companies "are still going to receive substantial payments and in comparison to other countries, it's still

going to be at higher amounts", Baron said. The Medicare programme is "a substantial market and just because you're making less of a profit doesn't mean you're making no profit".

To be eligible for price negotiations, only single-source, self-administered, brand-name drugs will be considered that have been on the market for 7 years, or 11 years for biological products, and without generic or biosimilar competitors before Sept 1, 2025. They must also be among Medicare's most expensive medications. So-called orphan drugs that are used to treat a single rare disease are excluded, as are drugs that cost Medicare less than \$200 million from June 1, 2022, until May 31, 2023; however, that limit applies only to the first group of ten drugs.

For each drug placed on the first-ten list, its manufacturer must provide detailed information by Oct 2, 2023, to the Centers for Medicare and Medicare Services (CMS), the agency that runs the Medicare programme, which will determine its maximum fair price. Among the required information is the drug's US sales volume and revenue, research and development costs, current per-unit production and distribution costs, federal funding, and any pending patent applications.

Although Janssen claims the negotiated price won't reflect a drug's value or efficacy, the law requires CMS to take into account its comparative effectiveness, whether it is a therapeutic advance, and if it is prescribed for conditions that have few alternative treatments.

Negotiations for the first ten drugs will continue until July 31, 2024, which is the deadline for manufacturers to decide whether to accept the maximum fair price. If a drug maker refuses, it would have to pay a large excise tax based on sales of the product. Instead of paying the tax, a company could decide to withdraw its drug from both the Medicare and Medicaid programmes, which provides health insurance to families that have

low income. That choice would mean losing access to programmes that provide prescription medicine for about 145 million beneficiaries, or roughly half the US pharmaceutical market.

The consequences for refusing to negotiate leave drug makers with few options, said Dickey. "So it's effectively a gun to the head of the manufacturer", she said. "It is the sort of cudgel that would require a manufacturer to agree to any price that the government sets."

Once a drug is selected for price negotiations, "the most direct way to remove it from consideration would be if a generic or biosimilar was approved by the Food and Drug Administration and became available for use, so there was direct competition between the selected drug and a generic or biosimilar equivalent", said Juliette Cubanski, Deputy Director of KFF's Program on Medicare Policy.

AARP, which represents nearly 38 million older Americans and strongly supported the Inflation Reduction Act, is "very pleased with how this process is playing out", said Leigh Purvis, Director of Health Care Costs and Access at the AARP's Public Policy Institute. She is also a co-author of the AARP's Rx Price Watch reports, which have documented steady increases in drug costs. "There are definitely some forces out there that would like to potentially neutralise what CMS is trying to do here and we very much want to make sure that doesn't happen."

While progress on the various legal challenges is not expected for several weeks, the drug price negotiation plan may face more formidable opponents outside the courtroom. Before the new prices take effect in 2026, there's a presidential election next year. If Republicans win the White House and a majority in Congress, they could promptly scrap the programme that they have long opposed, and abandon its promised savings.

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