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Big Drug Companies Are In Court To Stop Medicare From Negotiating Lower Prices In Order To Protect Sky-High Profits

Big Drug Companies Are Putting Greed Before Patients Once Again

Over the past year, drug company giants and their lobbying groups have sued the federal government in a joint effort to stop Medicare from negotiating for lower prescription drug prices — the most popular provision of the Inflation Reduction Act.

Several have already faced serious setbacks. Within the past month, a Delaware court dismissed drugmaker AstraZeneca's lawsuit and a Republican-appointed judge in Texas dismissed lobbying group PhRMA's lawsuit against the Medicare Drug Price Negotiation Program. In September, a Trump-appointed federal district judge in Ohio rejected a group of lobbyists represented by several Chambers of Commerce's request for a preliminary injunction to stop the negotiation program before it started and ordered for an amended complaint to be filed, rejecting the Chambers' claim that negotiation violates their due process rights under the Constitution. Despite facing rebuke from experts and judges from across the political spectrum, big drug companies and their allies are still pushing forward. Last week, PhRMA announced an appeal to the ultra-conservative Fifth Circuit Court of Appeals and four big drug companies jointly presented oral arguments before a New Jersey district court.

The Negotiation Program is projected to lower costs for seniors and save taxpayers tens of billions of dollars. Still, big drug companies are eager to protect their outsized prices and profits. Since the enactment of the Inflation Reduction Act, the drug companies have announced massive, above-expectation profits, bringing in hundreds of billions of dollars in revenue in 2023. Rather than making their lifesaving drugs affordable to patients, they compensated their CEOs with lavish multi-million-dollar salaries and spent billions rewarding shareholders through stock buybacks and dividends. They are only suing to stop Medicare from negotiating lower prices in an effort to protect their massive profits. While they rake in billions, U.S. drug prices are up to four times higher than prices in other high-income countries, leading patients in America to cut pills and skip doses to make ends meet.

What's At Stake?

Drug companies are seeking to end Medicare's new ability to negotiate lower prescription drug prices for Medicare beneficiaries. If they get their way, patients will pay more so the drug companies can make more money:

- **GONE: Medicare's power to negotiate lower prices** for the most popular and expensive prescription drugs. Under the Inflation Reduction Act, Medicare began negotiating prices

for 10 of the top 50 most expensive Part D drugs in February, which will take effect in 2026. The agency will add another 15 drugs taking effect in 2027 and 2028, and another 20 taking effect in 2029 and subsequent years.

- **GONE: $98.6 billion in Medicare savings** over the next decade from the drug negotiation program, which translates into savings for patients and taxpayers.

- **GONE: Lower Part D premiums and lower out-of-pocket drug costs** for certain Medicare beneficiaries who rely on qualifying drugs.

Who Is Behind These Lawsuits?

Six big drug companies have filed separate lawsuits against the federal government to overturn the Inflation Reduction Act, and multiple lobbying groups representing big drug companies have also filed lawsuits.

The Plaintiffs

AstraZeneca. AstraZeneca is a UK-based multinational drug company whose case was dismissed by a federal judge in Delaware. The company sells **Farxiga**, a drug used to treat diabetes, heart failure, and chronic kidney disease that is among the first ten drugs selected for negotiation.

- AstraZeneca charges U.S. patients 7–15 times more than patients in other high-income countries like Switzerland and Australia for Farxiga. Medicare negotiation will cut the price of an annual supply of Farxiga by approximately $1,992.
- Farxiga has cost Medicare nearly $6 billion and has made AstraZeneca nearly $21 billion in global revenue since its launch.
- AstraZeneca paid its CEO over $21 million last year, making him the highest-paid pharma CEO in Europe, and has spent nearly $35 billion on stock buybacks to reward investors since launching the drug.

Boehringer Ingelheim (BI). BI's case is pending before a Connecticut district court. BI manufactures **Jardiance**, a type 2 diabetes drug that is among the first ten drugs selected for negotiation.

- BI charges U.S. patients 6–14 times more than patients in other high-income countries like Switzerland and France for Jardiance. Medicare negotiation will cut the price of an annual supply of Januvia by approximately $1,836.
- Jardiance has garnered over $32 billion in sales for BI, costing Medicare over $14 billion since its launch.

Bristol Myers Squibb (BMS). BMS, which is suing in a New Jersey district court and gave joint oral arguments last week, manufactures blood clot drug **Eliquis**, one of the first ten drugs selected for negotiation.

- BMS charges U.S. patients 3–7 times more than patients in other high-income countries like Switzerland and Australia for Eliquis. Medicare negotiation will cut the price of an annual supply of Eliquis by approximately $1,488.
- Eliquis has garnered $69 billion in sales for BMS, costing Medicare at least $56 billion since its launch.
- BMS paid its CEO over $18.7 million last year and has spent billions on stock buybacks to reward investors since launching the drug.

Janssen Pharmaceuticals. A subsidiary of **Johnson & Johnson** which is suing in a New Jersey district court and gave joint oral arguments last week, Janssen manufactures or co-manufactures three of the first ten drugs selected for negotiation: blood cancer drug **Imbruvica**, psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis drug **Stelara**, and blood clot drug **Xarelto**.

- Johnson & Johnson charges U.S. patients 3–8 times more for Xarelto, 2–7.5 times more for Stelara, and 1.5–5 times more for Imbruvica than patients in other high-income countries like Australia. Medicare negotiation is estimated to cut the prices of an annual supply of each drug by thousands of dollars.
- The company paid its CEO over $13 million in 2022 and has spent tens of billions of dollars on stock buybacks to reward investors since launching the three drugs.
- Johnson & Johnson has reported a combined $113.7 billion in sales from the three drugs – $64.4 billion from Stelara, $23.7 billion from Xarelto, and $25.6 billion from Imbruvica.

Merck. Merck's case is before a Washington D.C. district court and is awaiting a decision. Merck manufactures type 2 diabetes drug **Januvia**, one of the first ten drugs selected for negotiation.

- Merck charges U.S. patients 5–20 times more than patients in other high-income countries like Canada and Germany for Januvia. Medicare negotiation will cut the price of an annual supply of Januvia by approximately $1,644.
- Januvia has garnered over $53 billion in sales for Merck, costing Medicare at least $32 billion since its launch
- Merck paid its CEO $52 million in total compensation in 2022 and has spent nearly $53 billion on stock buybacks to reward investors since launching the drug.

Novartis. Novartis, which is suing in a New Jersey district court and gave joint oral arguments last week, manufactures heart failure drug **Entresto**, one of the first ten drugs selected for negotiation.

    - Novartis charges U.S. patients 3–9.5 times more than patients in other high-income countries like Switzerland and Japan for Entresto. Medicare

negotiation will cut the price of an annual supply of Entresto by approximately $3,444.

- Entresto has garnered over $20 billion in sales for Novartis, costing Medicare at least $7 billion since launch.
- Novartis gave its CEO a 21 percent raise last year and has spent over $44 billion on stock buybacks to reward investors since launching the drug.

Novo Nordisk. Novo Nordisk, which is suing in a New Jersey district court and gave joint oral arguments last week, is a Denmark-based multinational drug company that sells **Fiasp**, a newer formulation of the diabetes drug known as NovoLog or NovoRapid which is among the first ten drugs selected for negotiation.

- Novo Nordisk charges U.S. patients 7–17.5 times more than patients in other high-income countries like Switzerland and Australia for Fiasp/NovoLog. Medicare negotiation will cut the price of an annual supply of Fiasp/NovoLog by approximately $360.
- Fiasp/NovoLog has cost Medicare at least $27 billion since its launch while making Novo Nordisk nearly $44 billion in global revenue.
- Novo Nordisk gave its CEO a 13 percent raise (around $10 million) last year and has spent $36 billion on stock buybacks to reward investors since launching the drug.

The U.S. Chamber of Commerce, and the Michigan, Ohio, and Dayton Area Chambers. The lawsuit is currently pending before an Ohio district court. In late September, a federal district court judge dealt a major blow to the plaintiffs, rejecting the Chamber of Commerce's motion for a preliminary injunction that sought to block the implementation of the Medicare drug negotiation program and suggesting he would reevaluate whether the Chamber had standing to bring the case following limited discovery, an amended complaint, and the government's renewed motion to dismiss. The judge ruled, "Because the Court, at this early juncture in the litigation, cannot tell with certainty whether or not Plaintiffs have standing to raise each of their claims, they necessarily cannot have a strong likelihood of success on the merits of their due process claim."

The Pharmaceutical Research And Manufacturers Of America (PhRMA). Drug company lobbying giant **PhRMA** is appealing to the Fifth Circuit Court of Appeals, a circuit "where law goes to die" packed with MAGA appointees and ultra-conservative judges that have relentlessly chased an extreme agenda threatening health care access. Several top drug companies are members of PhRMA – including **Amgen**, which manufactures rheumatoid arthritis, psoriasis, and psoriatic arthritis drug **Enbrel** which is among the first ten drugs selected for negotiation.

- Amgen charges U.S. patients 4–13 times more than patients in other high-income countries like Switzerland and Japan for Enbrel. Medicare negotiation will cut the price of an annual supply of Enbrel by approximately $30,912.

- Enbrel has cost Medicare at least nearly $22 billion since its launch while making Amgen over $84 billion in global revenue.
- Amgen paid its CEO over $21 million last year and has spent $89 billion on stock buybacks to reward investors since launching the drug.

Other plaintiffs in PhRMA's case receive direct financial support from PhRMA and have deep PhRMA connections. The National Infusion Center Association and the Global Colon Cancer Association are also joining PhRMA's lawsuit — both of which have aligned with PhRMA in previous lawsuits to protect big drug companies' ability to charge sky-high drug prices. The National Infusion Center Association received $120,000 from PhRMA in 2019, while the Global Colon Cancer Association got at least $50,000 and has spent years lobbying against a myriad of efforts to lower prescription drug prices ranging from importation to cancer drug pricing regulations. The Global Colon Cancer Association is led by several "corporate members" from pharmaceutical and biotech companies represented by PhRMA.

Why Plaintiffs' Legal Arguments Are Wrong

The plaintiffs assert several sweeping claims across the lawsuits – including under the First Amendment, the Fifth Amendment's Due Process and Takings Clauses, the Eighth Amendment's Excessive Fines Clause, and the Administrative Procedure Act – but experts and recent court rulings indicate that these meritless arguments are merely an attempt to maintain the status quo where drug companies can protect their massive profits by charging whatever they want at the expense of patients and taxpayers.

Plaintiffs' First Argument: Most plaintiffs argue that the Inflation Reduction Act violates the First Amendment. **BI** argues that signing a voluntary agreement to negotiate prices with Medicare "forc[es] BI to make untruthful statements about the fairness of mandated prices." **Bristol Myers Squibb** argues that the Negotiation Program violates the constitutional mandate that the government cannot conscript businesses to "parrot its preferred political messaging." Johnson & Johnson's **Janssen** argues that the Act "unconstitutionally conditions participation in Medicare and Medicaid" on Janssen by "forc[ing]" the company to endorse a "narrative that it 'agrees' to 'negotiate' Government-dictated prices, and that such prices are 'fair.'" **Merck** and **Novartis** argue that it compels speech. **Novo Nordisk** argues that the Program "forc[es] manufacturers to agree with the government," and plaintiffs for the **Chambers of Commerce** argue that signing a voluntary agreement to negotiate "force[s] that company to pretend that it 'agreed' to those prices."

Why The Plaintiffs Are Wrong: The Negotiation Program does not force drug companies to enter into agreements against their will; participation in Medicare is completely voluntary and the plaintiffs are attempting to stretch First Amendment doctrine beyond belief. As a federal district judge ruled in a similar case against the Inflation Reduction Act, "As there is no

constitutional right (or requirement) to engage in business with the government, the consequences of that participation cannot be considered a constitutional violation. Because Plaintiffs are not legally compelled to participate in the Program — or in Medicare generally — they have not shown a strong likelihood of success on the merits of their due process claim." PhRMA already lost a First Amendment challenge to California's drug pricing legislation in 2021, and the Supreme Court has previously explained that the government may attach certain conditions and language to funding and programs without violating the First Amendment, even where private actors disagree with those conditions and language.

Plaintiffs' Second Argument: Several plaintiffs also argue that the Inflation Reduction Act violates the Fifth Amendment's Takings Clause. **BI** argues that the voluntary program "affects a taking of private property without just compensation." **BMS** argues that its drugs are "protected personal property" that the Negotiation Program will "requisition" and "transfer…to Medicare beneficiaries" through "forced sales–coerced by the threat of draconian penalties." Johnson & Johnson's **Janssen** argues that the program "effects a physical taking of the company's Xarelto products," asserting that its patent-protected drug Xarelto should not be subject to a maximum fair price "because no dollar amount can fully compensate for what is, in reality, irreplaceable." **Merck** argues that the negotiation process constitutes a "seizure" through "forced sale[s]." **Novartis** argues that "The drugs themselves are—until they are sold—the manufacturers' personal property, and are therefore protected from uncompensated takings."

Why The Plaintiffs Are Wrong: First and foremost, Medicare is, and always has been, a voluntary program. Drug manufacturers – like physicians, hospitals, clinical labs, insurers, and other health care industry stakeholders – *choose to* participate in Medicare voluntarily. If a manufacturer of a selected drug does not want to negotiate the price of a selected drug or cannot come to an agreement on a negotiated price, among other options, the manufacturer can withdraw from participation, just as they could have done at any point since the law has been debated and enacted.

Because drug companies' participation in Medicare is not involuntary, it does not have a protected property interest in selling drugs to the government at prices the government will not agree to pay. The Negotiation Program in *no way requires* drug companies to sell selected drugs to Medicare at a specified price. Companies do not have any kind of property right to dictate the prices they pay while participating in a voluntary program. The notion that participating in market negotiation in a voluntary program somehow violates a company's constitutional right is nonsensical. The Act lets companies decide whether they wish to participate or not – and leaves it to companies to decide which path makes the most economic sense for them. So far, the courts have found this claim dubious.

Just last week, a federal judge ruled against **AstraZeneca**'s Fifth Amendment claim against the agency, ruling that it lacked merit because participating in the program is voluntary, not coercive:

"No one, however, is entitled to sell the Government drugs at prices the Government won't agree to pay. [...] On the contrary, 'participation in the Medicare program is a voluntary undertaking.'" As a federal judge in Ohio's Southern District ruled in the **Chambers of Commerce** case, "[P]articipation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice…pharmaceutical manufacturers who do not wish to participate in the Program have the ability—practical or not—to opt out of Medicare entirely."

Simply put, drug companies want to continue the status quo of having their greed unchecked by setting their own prices for their drugs and having Medicare be required to pay those prices. For too long, the industry has been able to exert its unparalleled power and deprive Americans of affordable drugs. The only reason they did not have to negotiate sooner is that Republicans included a provision in 2003 amendments to Medicare preventing negotiation in a concession to the powerful drug industry.

Plaintiffs' Third Argument: Several plaintiffs also argue that the Inflation Reduction Act violates the Eighth Amendment's Excessive Fines Clause. **BI** argues that the excise tax – imposed on manufacturers that refuse to agree to negotiated prices – is unconstitutional because "it imposes an 'exceedingly heavy burden'." **Novartis** argues that it imposes an excise tax on companies that choose not to enter into the negotiation process by refusing to submit statutorily required information to facilitate the negotiation process. They argue that the "draconian" penalty would be ruinous" and is "grossly disproportionate." Plaintiffs for the **Chambers of Commerce** argue that the excise tax penalties are "severe sanctions" that are "grossly disproportionate to the conduct at issue." **PhRMA** characterizes the agreed-upon penalty as "grossly disproportionate," "staggering," and "unconstitutional."

Why The Plaintiffs Are Wrong: The Supreme Court has famously ruled that Congress has broad and far-reaching authority to tax. In fact, several provisions in the Tax Code impose extremely large excise tax assessments, some even more than 100% of the amount involved. While the Eighth Amendment protects against "punitive" or "grossly disproportionate" taxes, the excise tax levied for refusing to comply with the Negotiation Program is neither a compulsory tax nor punitive. Drug companies can avoid the tax by complying with the Negotiation Program or simply exiting the Medicare and Medicaid programs.

Plaintiffs' Fourth Argument: Several plaintiffs argue that the Inflation Reduction Act violates the separation of powers and the Fifth Amendment's Due Process Clause. **BI** argues that the Negotiation Program "depriv[es] BI of its property interests without meaningful process" and "violates the unconstitutional conditions doctrine by conditioning BI's participation in Medicare and Medicaid on BI's consent to the deprivation of its property rights without due process of law." **Novo Nordisk** similarly characterizes the Negotiation Program as a "massive new price-setting scheme" that "provides none of the safeguards necessary to ensure separation of powers or to protect due process," and, "takes away those property interests, without affording

manufacturers a meaningful opportunity to be heard." Plaintiffs for the **Chambers of Commerce** argue that the Program "flouts bedrock principles of separation of powers and nondelegation, [and] exceeds Congress's enumerated powers," and **PhRMA** argues that the Program imposes "confiscatory" negotiated prices without providing adequate procedural protections through "administrative and judicial review," and constitutes an "impermissible arrogation of unfettered legislative power to CMS."

Why The Plaintiffs Are Wrong: Congress barring judicial review on administrative rulemaking is not a novel concept; there are at least 190 instances in federal code where Congress has barred judicial review. Medicare experts explain in an amicus brief that Medicare experts explain that courts have consistently upheld Congress's decision to limit judicial review within Medicare, recognizing that "tremendously complex Medicare payment programs cannot function if they are continually burdened by litigation at every step of implementation." Such experts also highlighted that the Medicare statute includes language barring judicial review of certain implementation decisions more than 60 times.

The Inflation Reduction Act is also not a price control statute, and the Constitution does not shield businesses from lawful price regulation. These are private companies, with enormous market power because they are the sole manufacturer of drugs that Americans depend on. The Act merely empowers HHS to negotiate – rather than blindly accept a price dictated by a drug company – the prices Medicare pays for a limited number of specified drugs. The Act does not set the market rate for drug prices. It establishes a mechanism by which drug manufacturers and the federal government mutually participate in a regulated market-driven process.

Plaintiffs' Fifth Argument: A few plaintiffs argue that the Inflation Reduction Act oversteps constitutional authority and violates the Administrative Procedure Act (APA). **BI** argues that CMS did not provide for ample notice and comment on the Manufacturer Agreement in violation of the APA, and **Novo Nordisk** argues that the Program violates the APA by "impos[ing] substantive requirements in addition to the statute's requirements" and "bind[ing] manufacturers to substantive obligations not subject to notice and comment rulemaking." Novo Nordisk also claims that the agency has "rewritten" the Act "to seize more powers than Congress authorized," pointing to the agency's decision to define "drug product" (for the purposes of negotiation) as including all drugs with the same active ingredient.

Why The Plaintiffs Are Wrong: First, there is a long-standing precedent for Congress delegating authority to negotiate lower prescription drug prices. Since 1992, the Department of Veterans Affairs (VA) has been able to negotiate prescription drug prices. The VA pays approximately 54 percent less for drugs than Medicare as a result.

Second, CMS has followed the necessary procedure designed by Congress in both the Inflation Reduction Act and the APA, outlining the process for selecting drugs for negotiation in its initial

guidance on implementing the program. After releasing initial guidance, CMS allowed the document to be scrutinized for public comment and released revised guidance responding to hundreds of comments from interested parties, providing detailed explanations for the definitions and procedures planned for implementation.

In its initial guidance, CMS explained that it identifies a drug's eligibility for the Negotiation Program based on the drug's active ingredient, and uses the earliest approval date to determine eligibility. CMS' determination of qualifying single source drugs falls under the purview outlined by the Inflation Reduction Act, which explicitly directs CMS to "use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended-release formulation, and not based on the specific formulation or package size or package type of the drug." The Act explicitly directs CMS to apply the negotiated price "across different strengths and dosage forms of a selected drug."

It is common practice for big drug companies to release multiple drugs with the same active ingredient, approved under separate applications by the Food and Drug Administration (FDA). If the Negotiation Program were limited to negotiating prices for a drug on a per-application basis, drug companies could slightly modify their products and license them under new applications, circumventing the lower negotiated price. Congress anticipated this and required the Negotiation Program to apply broadly across a drug's different strengths and dosages. Therefore, if CMS were to limit their determination of qualifying single-source drugs to drugs under a single-drug FDA application, CMS would be inconsistent with the statute.

Novo Nordisk's argument also rests on a hypothetical scenario in which CMS changes the terms of an agreement in an unspecified manner that violates the APA. The Negotiation Program, of course, does not force drug companies like Novo Nordisk to enter into agreements against their will. As a federal judge who ruled against AstraZeneca's similar APA challenge to the program wrote, "The harm alleged here is too vague to establish a cognizable injury."

What Happens Next

- March 22: The federal government's reply is due in Novo Nordisk's lawsuit
- March 27: The federal government's reply is due in Novartis' lawsuit

Here's What Legal & Health Experts Have Said About The Case

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- **Protect Our Care, Public Citizen, Patients for Affordable Drugs Now, Doctors for America and Families USA: Big Drug Companies' Claims "Must Be Rejected."** "Novo's theory is built on premises that drug companies are obligated to participate in Medicare and that the price they prefer to charge Medicare patients is the 'market' price from

which any reduction in price under the program must be evaluated. These premises are wrong. And absent any showing that the drug prices negotiated under the IRA program necessarily result in the deprivation of property interests, Novo's due process challenge must be rejected." [Novo Nordisk Inc. et al. v. Becerra et al., Amicus Curiae Brief, 1/31/24]

- **Nine Nationally Recognized Health Care Experts, Including Three Former Medicare Administrators: "Drug Price Affordability Is Essential."** "The Amici, nationally recognized experts in healthcare, healthcare finance, and Medicare, submit this brief to explain: that ensuring prescription drug price affordability is essential to the financial stability of the Medicare program; that the authority conferred on CMS by the DPNP to negotiate drug prices for the Medicare program is consistent with the authority that Congress has given CMS to limit excessive prices of other Medicare services; that this authority is also consistent with that given to other agencies to limit drug prices in other federal government programs; and, finally, that the courts have uniformly rejected challenges to the federal authority to limit prices for drugs and services paid by federal healthcare programs." [Novartis Pharmaceuticals Corporation v. Becerra et al., Amicus Curiae Brief, 1/19/24]

- **Seven Top Economists & Health Care Policy Scholars: Janssen Presents "An Overly Simplistic And Misleading Account Of The Prescription-Drug Market."** A group of seven top health care policy scholars and economists hailing from Harvard, Yale, Johns Hopkins, Boston University, and Georgetown wrote: "This brief shows how Janssen's contention reflects an overly simplistic and misleading account of the prescription-drug market. [...] [The Inflation Reduction Act] gives Medicare the authority to negotiate prices for drugs that have been on the market for at least 9-13 years. By doing so, it provides consumers with enough bargaining power to counter the pharmaceutical monopolist in establishing a price. The harm to true innovation is negligible because any drug eligible for negotiation will almost certainly have already recouped its investment many times over. This brief explains how, contrary to Janssen's contention, this brief explains how the Inflation Reduction Act pushes the drug market's dynamics closer to competitive equilibrium, not further away." [Janssen Pharmaceuticals Inc. v. Becerra et al., Amicus Curiae Brief, 10/23/23]

- **AARP and the AARP Foundation: "Many Older People Lack The Resources To Pay Exorbitant and Escalating Drug Prices."** "Ever-escalating drug prices have hit older people particularly hard, forcing millions to make devastating decisions because they cannot afford the medication they need. More than 50 million people are enrolled in Medicare Part D, the federal government's voluntary prescription drug benefit program for Medicare beneficiaries. On average, they take between four and five prescriptions per month and have a median annual income of just under $30,000. The vast majority have

chronic conditions requiring lifelong treatment. Many older people lack the resources to pay exorbitant and escalating drug prices. As a result, they are forced to choose between paying for their prescribed medication or paying for basic life essentials such as food, housing, or heat. Some older people skip doses, split doses, or forego filling their prescriptions altogether to make ends meet. Others sell everything they own and drain their resources because the price of their medication is beyond their reach" [Bristol Myers Squibb Company v. Becerra et al., Amicus Curiae Brief, 10/23/23]