



INITIAL LAWSUITS CLAIM IRA'S COMPELLED DRUG-PRICE NEGOTIATION IS BROAD BREAK WITH RULE OF LAW

by Matt Wetzel

In the past several weeks, four lawsuits have been filed in federal court challenging the constitutionality of the Inflation Reduction Act's ("IRA") Medicare drug price negotiation program. The program will subject top-spend drugs under Medicare to a forced and secret negotiation process without opportunity for redress or review. The process concludes with the Centers for Medicare & Medicaid Services ("CMS") setting a price for the drug that is at least 25-60% below the drug's average price, and likely even lower. Not ironically, this much lower price, derived from of a heavy-handed process, is called the "Maximum Fair Price."

CMS is set to select the first 10 drugs for the program on September 1, 2023. The four IRA lawsuits filed in June seek to challenge the program's validity under the Constitution and delay its implementation.

- *Merck v. Becerra* (U.S. District Court, District of Columbia) – June 6
- *Dayton Area Chamber of Commerce et al v. Becerra* (U.S. District Court, Southern District of Ohio) – June 9 (Plaintiff group led by U.S. Chamber of Commerce)
- *Bristol Myers Squibb v. Becerra* (U.S. District Court, District of New Jersey) – June 16
- *National Infusion Center Association, et al v. Becerra* (U.S. District Court, Western District of Texas) – June 21 (Plaintiff group led by Pharmaceutical Research & Manufacturers of America)

The complaints are remarkably crystal clear: the ends of the Medicare drug price controls (i.e. significantly reduced drug prices paid by Medicare) do not justify the means (i.e. a Congressional grant of unchecked power to a federal agency to compel private conduct and to take private property with no opportunity for judicial or administrative due process or review).

Among the many troubling attributes of the Medicare drug price negotiation program highlighted in the complaints include the requirement that companies must agree to participate in the negotiation program or otherwise face stiff excise taxes—i.e. penalties—that can amount to millions of dollars per day. Further, companies cannot simply pull out of the Medicare program if they don't want to participate in the negotiations. A company's withdrawal of every product from the Medicare Part D program alone can take up to 23 months, and so a manufacturer would be forced to participate and face the reduced price or face the penalty of the significant excise tax.

The complaints highlight the IRA's authorization of the Medicare program to impose significant price cuts on pharmaceuticals and biologics without any opportunity for judicial or administrative review. The program rules that the Medicare agency is currently drafting would call for strict confidentiality—

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whereby companies cannot discuss publicly any of the information exchanged with CMS during one of the few authorized negotiation meetings, including requiring companies to sign an attestation of destruction that all materials related to these meetings have been destroyed post hoc.

The complaints emphasize the IRA's granting to CMS full authority to set prices at will, not subject to any guardrails or guidelines. The agency will first look for a therapeutic alternative product to a selected drug, regardless of FDA approvals; and if that therapeutic alternative product is cheaper, CMS will start the negotiations there, at that lower price. There are no standards or guidelines corralling CMS's decision-making on this front.

Notably, several of the complaints focus on how Congress's actions and the current administration's actions have been deceptive—a "sham." The following passage from the Dayton/U.S. Chamber lawsuit speaks for itself:

Congress went out of its way to insulate the IRA's drug pricing regime from public accountability by camouflaging its delegation of unbridled regulatory power in novel and insidious ways.

This series of optical illusions includes the sham 'negotiation' process that, on examination, bears no resemblance to any genuine negotiation; the 'maximum fair price' provisions that require manufacturers to endorse the government's fiction that they are 'agreeing' to a price both parties consider 'fair'; the punitive and misnamed 'excise tax' that is so draconian not even the government expects it to produce any revenue These various ruses are intended to lull onlookers with the *appearance* of a fair, voluntary 'negotiation' process, but they are really just a façade for an unprecedented regime of extreme, unchecked delegation of power from Congress to the Executive, to be administered without judicial review of the results.

Each of these defects would be troubling and constitutionally suspect in its own right. Taken together, the combination of sweeping delegation with a total lack of corresponding safeguards creates an unconstitutional anomaly – ***an unaccountable structure that has slipped the bounds of the separation of powers.***

Dayton Area Chamber of Commerce, pp 38-39 (emphasis added).

The BMS complaint includes a similarly intriguing passage characterizing the true intent of the IRA, in the context of the compelled speech argument:

The Government's only apparent interest in compelling this speech is to reap political benefits by camouflaging forced sales as voluntary negotiations. Indeed, Congress could have authorized HHS to genuinely negotiate (or even unilaterally set) prices, or capped the prices at which manufacturers could sell their medicines, without sham 'negotiations' or 'agreements' coerced by tens or hundreds of millions of dollars in daily fines. The IRA's convoluted alternative regime appears designed to mislead the public, evade accountability, and promote an attractive political slogan. That is neither a compelling nor a legitimate government interest.

Bristol Myers Squibb, p. 28.

The complaints focus on how the IRA's price controls are shortsighted when it comes to understanding the scope and level of investment required for just one successful pharmaceutical product that saves and transforms lives. In my conversations with biotech and pharmaceutical executives and investors, a significant issue surrounding the IRA is the uncertainty of its applicability; that the law either has a detrimental impact to a particular molecule or asset's valuation, or that it's just too difficult to measure the potential impact of the IRA in the future. This is causing reevaluation of investment decisions and more selective decision-making when it comes to identifying and focusing resources on products.

Some companies are considering whether to launch their products in other countries before the United States to preserve and recoup the massive investments that go into just one blockbuster drug. And international companies are rethinking their commercialization strategies in the United States. All these anecdotal signs point to the IRA's slowing effect on the U.S. drug market—and this is just the beginning of the IRA's downstream effects, which if implemented as proposed will slow the pace of innovation in the United States and disincentivize research.

Across the four complaints filed to date, the parties collectively assert 6 key claims:

- 1. First Amendment Compelled Speech.** The First Amendment protects the right to refrain from speaking. Here, the IRA compels drug companies to speak by mandating that they enter negotiation agreements that require companies to endorse the Medicare prices as “maximum fair prices.” The government does not have a legitimate interest that justifies compelled speech.
- 2. Fifth Amendment Uncompensated Takings.** The Fifth Amendment requires that the federal government must pay just compensation when it takes private property. Here, the IRA will require drug makers to enter forced sales at significant price discounts under threat of coercion without just compensation. In fact, the IRA specifically requires HHS to (through unchecked means) impose drug prices that fall well below market value.
- 3. Fifth Amendment Due Process.** The Fifth Amendment prohibits the government from depriving a person of property without due process—i.e. notice and an opportunity to respond subject to procedural protections to prevent an erroneous deprivation of property. Pharmaceutical manufacturers have property interests in their patent rights and have expectations to be free from arbitrary or discriminatory price controls. The IRA deprives manufacturers of these rights by directing HHS to set Medicare prices at the lowest level, without procedural safeguards (like administrative or judicial review) and based on arbitrary standards for price setting.
- 4. Eighth Amendment Excessive Fines.** The Eighth Amendment prohibits the government from imposing excessive fines as punishment for an offense. Fines may be appropriate if they are not grossly disproportionate to the punishable conduct. The plaintiffs argue that the IRA imposes remarkably high penalties (i.e. the millions of dollars per day in excise taxes for refusing to participate in the program, amounting to up to 1900% of total daily revenues for all sales of the relevant drug) that are designed for a punitive purposes (i.e. agree to the Medicare negotiation program rates or face the penalty of the excise tax) without any sort of reprehensible conduct or offense.
- 5. Separation of Powers.** The IRA confers unlimited discretion to HHS in violation of the separation of powers with respect to drug pricing without an “intelligible principle” and without necessary constitutional safeguards to ensure accountability, rationality, and fairness, a “combination of sweeping power and the total lack of procedural protections [that] is unique and unprecedented.” Dayton, p. 36. Here, Congress failed to provide the appropriate checks and balances, such that it “creates an unconstitutional anomaly—an unaccountable structure that has slipped the bounds of the separation of powers . . . for no legitimate reason.” Dayton, p. 39.
- 6. No Legislative Authority.** The IRA's excise tax is not authorized by any power of Congress. Found in the Dayton/U.S. Chamber complaint, this argument asserts that none of the congressional powers enumerated in Article I of the Constitution would permit Congress to “impose a phony ‘excise tax’ on private companies to force

them to ‘agree’ to subject themselves to government price controls disguised as ‘negotiations’ or to ‘agree’ to whatever rock-bottom price [HHS] dictates.” Dayton, p. 50. The complaint argues that this is not a true “tax,” as it is not expected by CBO to produce any revenue. It is not an exercise of the commerce power, as it compels commerce—it does not regulate it.

All the plaintiffs are seeking declaratory and injunctive relief, and one could envision courts declaring the IRA’s Medicare drug price negotiation program unconstitutional, enjoining CMS from launching the program altogether, requiring delays in the negotiation process, carving out the excise tax, or some combination of outcomes. More suits are likely to be filed as the September 1 selection date draws nearer.

With minimal public stakeholder feedback, the lack of anchoring of pricing decisions in objective and scientific information, the inability for manufacturers to speak publicly about discussions with public agency officials, the lack of judicial or administrative review for any pricing decisions (or other decisions related to the program for that matter), the millions of dollars in potential excise taxes for refusing to participate, and the requirement to actively agree publicly that the “negotiated” price is the “maximum fair price” or be penalized—according to the lawsuits, the IRA’s implementation may just be Orwellian, Draconian, and Machiavellian all rolled up into one.