

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION AT DAYTON**

DAYTON AREA CHAMBER OF  
COMMERCE, *et al.*,

*Plaintiffs,*

v.

XAVIER BECERRA, *et al.*,

*Defendants.*

**No. 3:23-cv-00156-MJN-PBS**

**Judge Michael J. Newman**

**Magistrate Judge Peter B. Silvain, Jr.**

**PLAINTIFFS' RESPONSE TO DEFENDANTS' NOTICE OF  
SUPPLEMENTAL AUTHORITY**

The July 3 decision of the district court in *Boehringer Ingelheim Pharmaceuticals, Inc. v. Becerra*, 23-cv-01103 (D. Conn.) (“*BI*”), should have no effect on this Court’s decision in this case, for several reasons. *See* Dkt. 99 (Defendants’ notice of supplemental authority regarding *BI*); Dkt. 99-1 (*BI* slip op. (“*Op.*”)).

*First*, unlike Plaintiffs in this case, *BI* did not challenge the constitutionality of the statute under the Constitution’s separation of powers or as exceeding Congress’s enumerated powers.

*Second*, *BI*’s analysis improperly conflated the question whether participation in the Inflation Reduction Act (“*IRA*”) scheme at issue in this case is “voluntary” with whether participation in the pre-*IRA* Medicare program was voluntary. For example, the court described the “leading case” on the voluntariness issue as *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), a 30-year-old Takings Clause case that long predates the Supreme Court’s decision in *National Federation of Independent Businesses v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*), and that addresses a relatively minor modification to Medicare reimbursement bearing no resemblance to the transformation wrought by the *IRA*. *Op.* 21. Under *NFIB*, it is clear that participation in

Medicare as transformed by the IRA is not voluntary. *Compare, e.g.*, ECF 64 at 2, 4-5, 21 (emphasizing that regardless of whether participation in *Medicare* was or is voluntary, participation in *the IRA* scheme is not). As Judge Elrod observed at oral argument in *Nat'l Infusion Ctr. Ass'n v. Becerra*, 24-50180 (5th Cir. May 1, 2024): “This is not a challenge to Medicare reimbursement, this is a challenge to a novel, unprecedented price-setting program in an industry [where] the government is the 800-pound gorilla.” Oral Argument at 21:35–21:54. Moreover, the court did not address *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587 (6th Cir. 2001), which is binding precedent here.

Even so, for all of these errors and omissions, the *BI* court correctly saw through the government’s claim that companies can escape the IRA by “divesting” their interests in selected drugs. Op. 19–20. As the court explained, “[t]he government cannot evade a Fifth Amendment challenge by requiring manufacturers to choose between losing any property rights they have through government appropriation and losing them through divestment,” and indeed, “the Supreme Court has rejected this notion.” *Id.* at 19 (citing *Horne v. Dep’t of Agriculture*, 576 U.S. 350, 363 (2015)).

*Third*, in addressing the First Amendment issue, the opinion glossed over the argument that requiring manufacturers to use deceptive terms such as “agreement” and “maximum fair price” is compelled speech that is unnecessary to the operation of the IRA’s price controls. While acknowledging that “the IRA requires BI to communicate in various ways,” the opinion dismissed this forced speech as merely “incidental” to “typical price regulations.” Op. 31. As Plaintiffs here have explained, the reality is that the IRA is ““more than a mine-run price regulation”” because it combines price controls with gratuitous speech controls. Dkt. 90 at 53 (quoting *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47-48 (2017)). Tellingly, the government has never pointed to any similar speech controls in a price-regulation scheme—let alone controls that have

been upheld against a First Amendment challenge.

*Fourth*, with respect to the unconstitutional-conditions doctrine, the *BI* court expressed concern that applying it in this context would deprive the government of “the same leeway as private firms when it participates in the market in its proprietary capacity.” Op. 37. But as Plaintiffs have emphasized, “the IRA is plainly an exercise of sovereign regulatory power, not an example of ordinary market participation.” ECF 90 at 44. No private firm could evade scrutiny for wielding its dominance over nearly 50% of the market the way the government does under the IRA (including by demanding that manufacturers turn over extensive confidential business information), and no private firm could impose an 1,900% “excise tax” penalty on a party for refusing to come to an “agreement.” *Id.* The government cannot use its sovereign powers to make itself the “800-pound gorilla” and then avoid constitutional constraints by claiming to be like any ordinary participant in the market.

*Finally*, the district court dismissed the Excessive Fines Clause claim for lack of jurisdiction because it accepted the government’s dubious claim that a manufacturer “can bring a refund suit after incurring the [excise] tax on a single transaction” and hope that the IRS will show discretionary “forbearance with respect to collection” during the pendency of the suit. Op. 43–44. As Plaintiffs have explained, this idea is “unworkab[le].” ECF 90 at 25–26. The court failed to take into account the impracticability of cutting off the sale of vital medicines to Medicare beneficiaries, which would irreparably harm countless Americans as well as manufacturers’ own goodwill. *See id.* And the court overlooked that “excise tax” liability will continue to accrue while manufacturers make sales, even if the IRS condescends to not “immediately *collect*[]” that liability. *Id.*

In sum, the *BI* opinion should have no impact on this Court’s decision.

Dated: July 19, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 19, 2024, a true and correct copy of the foregoing Plaintiffs' Response to Defendants' Notice of Supplemental Authority was electronically filed with the Clerk of Court using the CM/ECF system which will send notification to all counsel of record.

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