

**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 31 decision of the district court in *Novo Nordisk, Inc. v. Becerra*, 23-cv-20814 (D.N.J.) (“*Novo*”)—following that court’s rejection of constitutional challenges to the Inflation Reduction Act’s price-control scheme in *Bristol Myers Squibb Co. v. Becerra*, No. 23-cv-3335 (D.N.J.) and *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 23-cv-3818 (D.N.J.) — should have no bearing on this Court’s decision here, for several reasons. *See* Dkt. 101 (Defendants’ notice of supplemental authority regarding *Novo*); Dkt. 101-1 (*Novo* slip op. (“Op.”)).

First, much of *Novo*’s briefing focused on challenges to CMS’s guidance implementing the IRA’s price-control program. Plaintiffs here, in contrast, challenge only the constitutionality of the statute and have not brought a constitutional or statutory challenge to CMS’s guidance. Much of the court’s decision in *Novo* is therefore not relevant to this case. And unlike Plaintiffs here, *Novo* did not challenge the constitutionality of the statute under the Constitution’s Excessive Fines Clause or as exceeding Congress’s enumerated powers.

Second, like the district court’s opinion in *BMS/Janssen*, the *Novo* opinion did not adequately grapple with the arguments that the program is coercive or violates the unconstitutional conditions doctrine. The district court explained that it “rejected these same arguments in *BMS-Janssen*”

because it found no “legal compulsion that obligates participation in either Medicare or the Program.” Op. 8–12. As in *BMS/Janssen*, however, the district court failed even to mention *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*). *NFIB* makes clear that unconstitutional coercion can occur without direct “legal” compulsion; in *NFIB*, although the federal government did not directly compel states to accept the Affordable Care Act’s transformational expansion of Medicaid, the Supreme Court held that the government could not indirectly pressure states to do so by leveraging preexisting Medicaid funding. *See* Dkt. 64 at 33–35. Other unconstitutional-conditions cases reflect the same principle. *See id.* at 30–32. Moreover, the district court ignored the argument that, in any event, manufacturers *are* legally required to remain in the program for at least 11 to 23 months, despite the government’s attempt to rewrite the statute through non-binding guidance. *See id.* at 28–30.

Third, the *Novo* opinion misconstrued the relevant separation-of-powers and nondelegation principles and failed to consider how a lack of statutory standards and a lack of judicial review of key agency decisions combine to make the program an unprecedented delegation of power. *See* Op. 13–17. Reducing the separation-of-powers inquiry to a toothless application of the “intelligible principle” test, the court found sufficient that Congress had established an administrative price-control program, set a *ceiling* for the so-called “maximum fair price” (but not a *floor*), and identified non-binding “factors” for the agency to consider. Op. 15–16. The court ignored that the statute defines the “maximum fair price” as whatever price CMS selects (without judicial review) and thus grants an agency unprecedented price-setting discretion. *See* Dkt. 60 at 47–59. The court also mistakenly treated the absence of judicial review as irrelevant. *See* Op. 17; Dkt. 60 at 49–53.

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

Dated: August 8, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 8, 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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