## UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

DAYTON AREA CHAMBER OF COMMERCE et al.,

Plaintiffs,

v.

XAVIER BECERRA et al.,

Defendants.

Civil Action No. 3:23-cv-00156-MJN-PBS

Judge Michael J. Newman

Magistrate Judge Peter B. Silvain, Jr.

## **DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY**

Defendants respectfully submit this notice of supplemental authority to inform the Court of a July 31, 2024 Opinion by the United States District Court for the District of New Jersey in *Novo Nordisk Inc. v. Becerra*, No. 23-cv-20814 (D.N.J.) (Quraishi, J.). A copy of that decision is attached to this Notice as Exhibit A.

Like Plaintiffs here, the plaintiffs in *Novo Nordisk* raised Due Process Clause and separation of powers challenges to the Drug Price Negotiation Program created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169. Indeed, several of the arguments advanced by plaintiffs in *Novo Nordisk* were substantively identical to the arguments presented in this case.

As for the Due Process Clause, the district court agreed with every court to consider the question, including this Court, "that because Plaintiffs' participation in the Program is voluntary, Plaintiffs do not have a protected property interest to sell drugs to Medicare at their professed 'fair market value' nor do they have a property interest in their expectation that they will continue selling their drugs to Medicare at a fair market value." Ex. A at 13. "Accordingly, Plaintiffs cannot demonstrate that the Program deprives them of a protected interest and therefore their Due Process Clause claim fails as a matter of law." *Id.* 

As for the separation of powers, the *Novo Nordisk* plaintiffs' claim (like Plaintiffs' claim here) was "largely premised on the nondelegation doctrine." *Id.* at 13. And the *Novo Nordisk* plaintiffs (like Plaintiffs here) also "argue[d] that nondelegation concerns are heightened by 'Congress's decision to withdraw judicial review of CMS's price-setting decisions." *Id.* (citation omitted). The district court rejected those arguments, holding "that the IRA does not violate the nondelegation doctrine and it does not violate separation of powers." *Id.* at 17.

First, the district court explained that, although "[t]he statute sets forth a broad delegation to CMS to negotiate maximum fair prices for selected drugs," it "also narrowly defines relevant terms, sets forth the timelines for the various applicability periods, and provides CMS with guidance during the price negotiation phase." *Id.* at 16; *see also id.* ("Finding that the IRA fails to delegate an intelligible principle to CMS would disturb nearly century-long precedent.").

Second, the district court held that "Plaintiffs' argument that the nondelegation doctrine is violated because CMS's decisions are not subject to judicial review is misplaced." *Id.* at 17. The court agreed with the government that "the nondelegation doctrine focuses on 'the power Congress has delegated to the Executive Branch, *on the front end*—not whether the exercise of that power is subject to otherwise-unrelated constraints, *on the back end*." *Id.* (citation omitted). And it recognized that "courts have consistently considered statutes that preclude judicial review and have not indicated that such preclusion violates the nondelegation doctrine." *Id.* 

The district court in *Novo Nordisk* thus rejected these (and other) challenges and entered judgment in favor of the government on all claims.

Dated: August 2, 2024 Respectfully submitted,

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