

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC.,

Plaintiff,

v.

XAVIER BECERRA, U.S. Secretary of
Health and Human Services, *et al.*,

Defendants.

Civil Action No. 1:23-cv-01615-CKK

DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY

Defendants respectfully submit this notice of supplemental authority to inform the Court of a March 1, 2024 Memorandum Opinion by the United States District Court for the District of Delaware in *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:23-cv-00931-CFC, 2024 WL 895036 (D. Del.), a copy of which is attached to this Notice.

The plaintiffs in *AstraZeneca* challenged the constitutionality of the Drug Price Negotiation Program created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169, and the lawfulness of guidance promulgated by the Centers for Medicare & Medicaid Services to implement that Program. In particular, the *AstraZeneca* plaintiffs alleged that the Negotiation Program violated the Fifth Amendment's Due Process Clause.

In a March 1, 2024 opinion, the court granted summary judgment in favor of the Government on all claims. As relevant here, the court reached the merits of the due process claim and determined that it "fails as a matter of law" because—among other things—"[n]either the IRA nor any other federal law requires *AstraZeneca* to sell its drugs to Medicare beneficiaries." *AstraZeneca*, 2024 WL 895036, at 41. "On the contrary," the court held, "participation in the Medicare program is a voluntary undertaking." *Id.* at 41 (citing *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, --- F. Supp. 3d ---, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023)). Notably, the

court reached this conclusion over the plaintiffs’ objection that Medicare accounted for such a large part of the “potential market for prescription drugs” that they had “a powerful incentive” to participate. *Id.* at 43. Access to Medicare, the court observed, is not a “gun to the head” but rather “is a potential economic opportunity that [the plaintiffs are] free to accept or reject.” *Id.* at 44.

Dated: March 4, 2024

Respectfully submitted,

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