



United States Department of Justice

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March 4, 2024

Hon. Zahid N. Quraishi
United States District Judge
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street Room 2020
Trenton, NJ 08608

Re: *Bristol Myers Squibb Co. v. Becerra*, No. 23-cv-3335; *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 23-cv-3818; *Novartis Pharmaceuticals Corp. v. Becerra*, No. 23-cv-14221; and *Novo Nordisk Inc. v. Becerra*, No. 23-cv-20814.

Dear Judge Quraishi:

Defendants in the above-captioned cases 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, which is attached as Exhibit A.

Like plaintiffs in these cases, the plaintiffs in *AstraZeneca* challenged the constitutionality of the Drug Price Negotiation Program (“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 (“CMS”) to implement that Program. In particular, the *AstraZeneca* plaintiffs alleged that the Program violated the Fifth Amendment’s Due Process Clause and that two separate provisions of CMS’s guidance improperly interpreted the statutory term “qualifying single source drug” in violation of the Administrative Procedure Act (“APA”).

In the March 1, 2024 decision, the court granted summary judgment in favor of the Government on all claims. As to the APA claims, the court held that “AstraZeneca does not have Article III standing to challenge the lawfulness of the guidance” because the manufacturers could not show that they were concretely affected by the aspects of the Revised Guidance they challenged. *See* Ex. A at 1; *see also id.* at 20–34. The court reached the merits of the due process claim and determined that it “fails as a matter of law” because the plaintiffs failed to “identify[] a property interest protected by the Constitution that is put in jeopardy by the Program.” *Id.* at 44.

As the court detailed, “[n]o one . . . is entitled to sell the Government drugs at prices the Government won’t agree to pay.” *Id.* at 40 (citing *Coyne-Delany Co. v. Cap. Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980)). And “[n]either the IRA nor any other federal law requires AstraZeneca to sell its drugs to Medicare beneficiaries.” *Id.* at 41. “On the contrary,” the court held, “participation in the Medicare program

is a voluntary undertaking.” *Id.* at 41 (quoting *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991)). 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 noted, 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.

Respectfully submitted,

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cc: All Counsel of Record (via ECF)