

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., and
MERCK SHARP & DOHME LLC,

Plaintiffs,

v.

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

Defendants.

Civ. No. 1:23-01615 (CKK)

RESPONSE TO DEFENDANTS’ NOTICE OF SUPPLEMENTAL AUTHORITY

Plaintiffs (Merck) respectfully respond to Defendants’ notice of supplemental authority (ECF 64) regarding *AstraZeneca Pharmaceuticals LP v. Becerra* (D. Del. Mar. 1, 2024).

The *AstraZeneca* plaintiffs claimed the Drug Price Negotiation Program violates the Due Process Clause by impairing their “ability to sell [their] drugs to Medicare at prices above the ceiling prices ... established by the IRA.” (Op. 38.) The district court rejected that claim because “[n]o one ... is entitled to sell the Government drugs at prices the Government won’t agree to pay.” (Op. 40.) The plaintiffs therefore failed to identify “the deprivation of a constitutionally protected property interest,” and their Due Process claim “fail[ed] as a matter of law.” (Op. 44.)

Merck’s claim under the Takings Clause is fundamentally different. Merck does not assert a right to sell its drugs to Medicare at a *market* price; rather, it asserts a right *not to be compelled* to sell its drugs to Medicare at the *government-dictated* price. ECF 52 at 12. It is the drugs themselves—which everyone concedes are property protected by the Takings Clause—that are being taken by the Program. The *AstraZeneca* court actually confirmed the premise of this claim by acknowledging that the Program compels manufacturers to “make the selected drug available to Medicare beneficiaries” at the government-dictated discounted price. (Op. 9.)

The Government points to the court’s statement that “neither the IRA nor any other federal law requires AstraZeneca to sell its drugs to Medicare beneficiaries.” (Op. 41.) In context, however, that language referred to AstraZeneca’s ability to avoid IRA penalties by withdrawing all of its products from Medicare and Medicaid. And, in the Takings Clause context, the Supreme Court has rejected attempts by the Government to justify physical takings as “voluntary” on the ground that a party could avoid the seizure by withdrawing from the relevant market. *See, e.g., Horne v. Dep’t of Agric.*, 576 U.S. 350, 356, 365-67 (2015). The *AstraZeneca* court did not consider those precedents because no Takings Clause claim was presented in that case. Nor did the court consider the established limits on the Government’s ability to “condition” Medicare participation on forfeiture of constitutional rights, because the plaintiffs had not identified any threshold deprivation of constitutional rights in the first place.

Finally, the *AstraZeneca* decision also does not purport to speak to Merck’s claim under the First Amendment’s compelled speech doctrine.

Dated: March 4, 2024

Respectfully submitted,

/s/ Yaakov M. Roth

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