

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., 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 82) regarding *Boehringer Ingelheim Pharmaceuticals, Inc. v. HHS*, No. 24-2092 (2d. Cir. Aug. 7, 2025). Defendants are correct that *Boehringer* involved the same claims as Merck's suit. But the Second Circuit erred, and this Court need not—and should not—repeat its mistakes.

The linchpin of the Second Circuit's analysis—including its rejection of the Takings and First Amendment claims—was its holding that *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), dictates that participation in the Program is "voluntary." *See* Op. 25 ("The threshold question ... is whether participation in the Negotiation Program is voluntary. Under *Garelick*, the answer is yes."); *see also id.* at 24-28, 31, 39. Setting aside the merits of that reading of *Garelick* (*see* ECF 53 at 32), this Court is not bound by *Garelick* or any other Second Circuit precedent. Instead, D.C. Circuit precedent dictates that a statutory requirement to hand over private property does not become "a voluntary exchange" merely because the property owner theoretically has other costly "options." *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1235 (D.C. Cir. 2023); *see* ECF 53 at 8-10. That is the controlling circuit precedent here.

In all events, the Program is not “voluntary” under Supreme Court precedent. *See* ECF 23 at 37-48; ECF 53 at 20-30. As the Second Circuit recognized, the IRA puts pharmaceutical manufacturers to the “choice” of either surrendering *one product* at the Government’s “final word” price or “withdrawing *all its products* from Medicare and Medicaid.” Op. 15, 18 (emphasis added); *accord* ECF 53 at 13-14; *contra* ECF 25 at 7, 15, 17 (Government suggesting a manufacturer could withdraw only the *selected* drug). That so-called “choice”—fork over one product at a below-market rate, or abandon half of the domestic market—is “illusory,” *United States v. Butler*, 297 U.S. 1, 71 (1936); the supposed “voluntary exchange” exists “merely in theory,” not “in fact,” *NFIB v. Sebelius*, 567 U.S. 519, 581 (2012). In dismissing *NFIB* as irrelevant to “private parties,” Op. 29-30, the Second Circuit both misread *NFIB* and ignored the Supreme Court’s recent and repeated admonition that its “spending-power” precedents apply “similar principles to state and private recipients of federal aid.” *See, e.g., Medina v. Planned Parenthood S. Atl.*, 145 S. Ct. 2219, 2233 n.4 (2025); *see also* ECF 23 at 38-41; ECF 53 at 23-25.

Having deemed the Program “voluntary,” the Second Circuit rejected Boehringer’s Takings claim, Op. 30-35, including the manufacturer’s analogy to *Horne v. USDA*, 576 U.S. 350 (2015), *see* Op. 33-35. But that court did so based on a misunderstanding of the Program, which it characterized as merely “setting the price that [the Government] would pay for certain services.” Op. 33. The IRA does not impose a *price cap* on Januvia sales to Medicare. Instead, it compels Merck to *continue selling* Januvia at the Government’s price for as long as Merck wishes to preserve Medicare and Medicaid access for *any* of its products, Januvia or otherwise. *See* 42 U.S.C. § 1320f-2(a)(3); ECF 23 at 16-18; ECF 53 at 11-16. Like *Horne*, then, the Program *does* involve the “actual seizure of personal property” (Op. 33)—compelling a manufacturer to ship its product at a 50% discount is the same as forcibly hauling away half its stock. *See* ECF 53 at 11.

The Second Circuit then summarily rejected the plaintiff’s First Amendment claim under *Garelick*. Op. 38-39. But as just discussed, Merck was “compelled to” sign the IRA’s Agreement (*contra* ECF 82 at 2); withdrawing all of Merck’s products from half of the American market was no option at all. Notably, the Second Circuit did not otherwise address the merits of the First Amendment claim. *See* Op. 42 n.13. Its analysis thus rises or falls with its reading of *Garelick*—and that reading cannot be squared with Supreme Court precedent. *See supra* at 2.

Turning to the unconstitutional-conditions doctrine, the Second Circuit only compounded its errors. Op. 42-46. On the First Amendment side, the court overlooked that “compelling a [funding] recipient to adopt a particular belief as a condition of funding,” or to broadcast “the Government’s view on an issue,” is *never* permissible—even where the “belief” or “issue” relates to the spending program. *Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.*, 570 U.S. 205, 218 (2013); *see also* ECF 23 at 44-45; ECF 53 at 43-45. The IRA does precisely that by requiring Merck to express its assent to the Program’s various false premises—including the notion that the price dictated by the Government is the “maximum fair price” for Januvia. *See* ECF 53 at 35-36.

On the Takings side, the Second Circuit suggested that the Program’s property exaction is permissible merely because it operates “within the four corners of Medicare.” Op. 46. But courts must examine “nexus” *and* “proportionality” lest Congress exact property through “coerci[on].” *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). Far from a special feature of “land use permitting” (Op. 46 n.15), this requirement reflects “the unconstitutional conditions doctrine” more broadly. *Sheetz v. Cnty. of El Dorado*, 601 U.S. 267, 275 (2024). And that doctrine prohibits *any* attempt to “exact private property without paying for it.” *Id.* By leveraging the Government’s legislated monopsony power to compel access to Januvia at below-market prices, the Program does exactly that. *See* ECF 23 at 46-48; ECF 53 at 28-30.

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Merck respectfully reiterates its request that the Court rule as swiftly as possible in this first-filed IRA challenge, now fully briefed on summary judgment since November 29, 2023. *See* ECF 63. Respectfully, Merck's case now lags far behind that of every other manufacturer, and the Program's regime of forced sales is set to take effect in January 2026, well in advance of when Merck could obtain full appellate review. If the Court agrees with Merck, *Valancourt*, and Supreme Court precedent, it should promptly hold that the Program is unconstitutional. And if it agrees with *Boehringer*, then it should speed this challenge on its way to the D.C. Circuit.

Dated: August 13, 2025

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