

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 85) regarding *Bristol Myers Squibb Co. v. HHS*, No. 24-1820 (3d Cir. Sept. 4, 2025), and *Janssen Pharmaceuticals Inc. v. HHS*, No. 24-1821 (3d Cir. Sept. 4, 2025). Defendants are correct that these cases involved the same claims as Merck's suit. For many of the reasons given in Judge Hardiman's thoughtful dissent, however, the panel majority erred in resolving them. This Court should follow his lead and recognize the Program's fatal constitutional defects.

First, the majority's conclusion that the Program is "voluntary" fails because a manufacturer has no practical ability to avoid its mandates without paying massive penalties. As Merck has explained, withdrawing all of its products from Medicare and Medicaid—which the Third Circuit correctly recognized is the *only* way to avoid excise-tax liability (Maj. Op. 20, 23)—is no option at all. Doing so would devastate Merck's domestic business and cripple its ability to fund critical research—all while leaving millions of Americans without access to their prescription medications. Far from a routine, voluntary decision to "stop doing business with the government," Maj. Op. 20, that Hobson's choice is utterly "illusory" for manufacturers like Merck. *United States v. Butler*, 297 U.S. 1, 71 (1936); *see* ECF 23 at 37-48; ECF 53 at 20-30.

Moreover, as Merck has explained, even that *theoretical* exit option was unavailable to manufacturers hoping to escape the Program’s first round of drug selections and forced sales. *See* ECF 23 at 42-44; ECF 53 at 23. To do so, as Judge Hardiman detailed in his dissent, a manufacturer would have needed to announce its intention to terminate its Medicare and Medicaid agreements before the IRA was even enacted. *See id.*; Dissent 11-21. And while *CMS* purported to fix this exit barrier in a guidance document, its convoluted and atextual rescue mission only confirms that *Congress* was not offering a “deal” that could be “voluntarily” accepted: It was mandating access to prescription medications at below-market rates. *See* ECF 23 at 44; Dissent 18-22.

In addition, while the Government (ECF 85 at 1) characterizes the Third Circuit as rejecting the analogy between the Program and the statute in *Valancourt Books, LLC v. Garland*, 82 F.4th 1222 (D.C. Cir. 2023), the majority did nothing of the sort. Instead, it just cited *Valancourt* for the general proposition that there is no taking “*when a party gives up private property as part of a voluntary exchange with the government.*” Maj. Op. 21 (emphasis added). In doing so, it did not address Merck’s argument that, as in *Valancourt*, there is no such “voluntary exchange” in the IRA. ECF 53 at 8-10, 22-23. This Court, however, must follow, not ignore, D.C. Circuit precedent.

Second, the Third Circuit’s rejection of the plaintiffs’ First Amendment compelled-speech claim is equally unpersuasive. The majority held that the Program’s “agreements” merely regulate “conduct,” not “speech.” Maj. Op. 36, 40-41. But as Judge Hardiman explained, the Program “does the opposite: it compels speech as a means to regulate conduct.” Dissent 32; *see also* ECF 53 at 36 (“Here, the Program directly compels speech (the agreement), and that speech incidentally affects conduct (by accepting the obligation to provide the drugs).”). This Court should not join the Third Circuit in the remarkable view that a mandate to *speak* does not burden *speech*, so long as that speech compulsion effectuates some other statutory requirement.

The Third Circuit also determined that even if the Program compels manufacturers to sign its agreements, those agreements are not “expressive.” Maj. Op. 42. But that is wrong: Mirroring Merck’s arguments in this case, Judge Hardiman explained that under Supreme Court precedent, “signing a document—including government funding agreements—can constitute expression.” Dissent 34; *see* ECF 23 at 29-30; ECF 53 at 38-42. And here, the message is unmistakable: Inking an IRA agreement necessarily (mis)informs the public that the manufacturer and CMS have “agreed” on a “maximum fair price” through voluntary “negotiation.” Nor did the Third Circuit ever identify any alternative explanation for Congress’s decision to effectuate the IRA’s mandates through signed “agreements.” That is because none exists: Congress, “in an Orwellian fashion,” “forced” Merck and other manufacturers “to sign Agreements that include representations they have abjured from the start.” Dissent 36. In short, the Program requires Merck “to convey the Government’s message about a subject of great political significance and debate.” Dissent 37. The First Amendment does not tolerate that result. *See* ECF 23 at 22-33; ECF 53 at 34.

Third, the Third Circuit held that Congress is entitled to leverage its spending power to extract speech from private funding recipients, provided that its “speech compulsion does not reach outside of the contours of the Program.” Maj. Op. 47. As Merck has explained, that view cannot be reconciled with *Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.*, 570 U.S. 205, 214 (2013). *See* ECF 23 at 44; ECF 53 at 43-45. Indeed, the majority’s circular approach would permit Congress to compel speech on any topic by simply embedding the mandate in a federal spending scheme. That reasoning is alien to the First Amendment: If Congress “compels expressive, content-based speech,” its law “triggers strict scrutiny”—full stop. Dissent 39. And there is no justification for the IRA’s “agreements,” which “gratuitously compel[] speech in violation of the First Amendment.” Dissent 40; *accord* ECF 23 at 33; ECF 53 at 34.

* * *

The Third Circuit’s ruling provides yet another reminder of how far Merck’s suit has fallen behind its peers: The plaintiffs in *Bristol Myers Squibb* and *Janssen* filed their complaints *after* Merck, yet they are in a position to seek Supreme Court review before this challenge has even reached the D.C. Circuit. With the Program’s regime of forced below-market sales poised to take effect in January 2026, Merck respectfully reiterates its request that the Court rule as swiftly as possible on the parties’ cross-motions for summary judgment.

Dated: September 10, 2025

/s/ Brinton Lucas

Brinton Lucas (D.C. Bar 1015185)

JONES DAY

51 Louisiana Avenue N.W.

Washington, DC 20012

(202) 879-3939

John Henry Thompson* (D.C. Bar 90013831)

JONES DAY

1221 Peachtree St., NE, Suite 400

Atlanta, GA 30361

(404) 581-8657

**Not admitted in Georgia.*

*Practicing under the supervision of
members of the Georgia Bar.*

Counsel for Plaintiffs