

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 No. 70) regarding *Boehringer Ingelheim Pharmaceuticals, Inc. v. HHS* (D. Conn.) (*BI*). The *BI* decision does involve the same claims as this case, but the court's ruling was wrong.

As to the Takings Clause, the *BI* court held that a manufacturer's option to withdraw all of its drugs from both Medicare and Medicaid rendered the Program "voluntary" and thus immune from constitutional scrutiny. Op. 21-30. But that categorical approach is irreconcilable with the Supreme Court's unconstitutional conditions doctrine, which limits Congress's power to require the surrender of constitutional rights as a condition of a "voluntary" program. *See Sheetz v. Cnty. of El Dorado*, 601 U.S. 267, 273-75 (2024); *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013); *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 674, 581-85 (2012); *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 834-37 (1987). As Merck has explained, the Program fails that doctrine for a host of reasons. ECF No. 23 at 35-48. The *BI* court believed its contrary holding was compelled by Second Circuit precedent. Op. 26 ("I am required to follow Second Circuit precedent unless and until it is overruled . . ." (cleaned up)). Even if so, D.C. Circuit precedent supports Merck. *See Valancourt Books, LLC v. Garland*, 82 F.4th 1222 (D.C. Cir. 2023).

As to the First Amendment, *BI* held that the Program’s compelled “agreements” are merely incidental burdens on speech. Op. 31. Not so. The “agreements” are directly mandated by statute and reflect an important part of the Government’s campaign to win public support. *See* ECF No. 23 at 26-33. Notably, *BI* was unable to explain why Congress structured the Program in such a circuitous way—instead of just giving CMS the authority to set prices and mandate sales—if not to falsely suggest to the public that the manufacturers had consented to the Program.

With *BI* now decided, every other court handling a similar challenge to the Program—all of which were filed after this one—has issued a merits or other dispositive ruling. The District of Delaware agreed to, and did, adjudicate a challenge to the Program by March 1, 2024. *AstraZeneca Pharms. LP v. Becerra*, No. 23-cv-931, 2024 WL 895036 (D. Del.). The District of New Jersey resolved two parallel challenges roughly 4 months after briefing concluded; the resulting appeal is already underway. *Bristol Myers Squibb Co. v. Becerra*, et al., No. 23-cv-3335 (D.N.J. Apr. 29, 2024), *appeal pending*, No. 24-1820 (3d Cir.). And *BI* was resolved less than two weeks after oral argument. Merck respectfully requests that this Court give priority consideration to resolving this case as soon as practicable so that the Program’s constitutionality can be adjudicated by the D.C. Circuit and Supreme Court before its regime of forced sales takes full effect in 2026.

Dated: July 17, 2024

Respectfully submitted,

/s/ Yaakov M. Roth

Yaakov M. Roth (D.C. Bar 995090)

Megan Lacy Owen (D.C. Bar 1007688)

Brinton Lucas (D.C. Bar 1015185)

John Henry Thompson (D.C. Bar 90013831)

Louis J. Capozzi III (D.C. Bar 90018764)

JONES DAY

51 Louisiana Avenue N.W.

Washington, DC 20012

(202) 879-3939

*Counsel for Plaintiffs*