

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT**

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES *et al.*,

Defendants.

Civil Action No. 3:23-CV-01103-MPS

**PLAINTIFF’S RESPONSE TO DEFENDANTS’
NOTICE OF SUPPLEMENTAL AUTHORITY**

Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. (“Boehringer”) writes in response to Defendants’ Notice of Supplemental Authority, ECF 105, which addresses a recent unpublished decision by the U.S. District Court for the District of New Jersey regarding other challenges to the Inflation Reduction Act’s Drug Price Negotiation Program (the “Program”). *See Bristol Myers Squibb Co. v. Becerra*, No. 23-3335, 2024 WL 1855054 (D.N.J. Apr. 29, 2024) (“*BMS*”).

In *BMS*, the district court concluded that the Program does not effect a taking because manufacturers’ participation is supposedly voluntary; does not compel speech in violation of the First Amendment because the Program regulates conduct and has only “incidental” effects on speech; and does not violate the unconstitutional conditions doctrine because it does not violate the First or Fifth Amendments. ECF 105-1, at 7–18, 19–26. The court’s unpublished, out-of-circuit order—which has already been appealed—overlooks important parts of the analysis and is not persuasive with respect to the issues presented here.

In this case, Boehringer presents distinct arguments and raises additional claims that were not raised by the *BMS* plaintiffs and consequently are not addressed by the *BMS* decision.

Moreover, while the claims in this case overlap in part with those in *BMS*, the briefing here explains why summary judgment should be granted for Boehringer. *See* ECF 28-1, ECF 92.

First, *BMS* does not address several of the reasons why the Program not only coerces, but compels, manufacturers' participation. *See* ECF 92 at 6–18. For example, *BMS* does not consider the effect of *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (“*NFIB*”), and earlier Supreme Court cases holding that a “regulation is not in fact voluntary,” and the “asserted power of choice” is “illusory,” where Congress uses “coercion by economic pressure” “to induce [a regulated company] to surrender [its] independence of action,” *United States v. Butler*, 297 U.S. 1, 70–71 (1936). This “economic dragooning” analysis is applicable to private actors such as Boehringer. *See* ECF 28-1 at 34–35; ECF 92 at 10–11. Indeed, Boehringer has filed a detailed, sworn declaration establishing that the Program is not voluntary as applied to Boehringer. *See* ECF 28-2 ¶¶ 7–24. The *BMS* court had no occasion to consider that evidence, nor did it meaningfully engage with the factual record presented in that case.

As another example, the *BMS* court erred by dismissing as “inapposite” the Supreme Court’s analysis in *Horne v. Department of Agriculture*, 576 U.S. 350 (2015). Much like the regulations at issue in *Horne*, the Program requires manufacturers to grant the Government access to a particular product without paying a market price, on pain of harsh economic sanctions. *BMS* distinguishes *Horne* based on several superficial factual differences (such as whether or not trucks arrive to collect physical goods) but does not explain why those differences affect the takings analysis. *BMS* also overlooks important similarities between the Program and the regulatory scheme in *Horne*, such as the fact that the raisin growers in *Horne* also had options to avoid the exaction (such as changing crops or selling grapes instead of raisins). The existence of these purported exit options did not change the result that there was a taking, *Horne*, 576 U.S. at 365,

and the same is true here. ECF 92 at 9–10, 12. As Boehringer’s briefing shows, what matters is whether the Program appropriates property rights, not the specific form the appropriation takes.

Second, *BMS* does not cite any authority for the novel proposition that the Government may force a speaker to utter a message so long as that requirement is part of a scheme that also regulates conduct. *Compare* ECF 105-1 at 20–25, *with* ECF 92 at 31–35. Moreover, the *BMS* court’s dismissal of the Program’s compelled use of terms like “maximum fair price” as merely “reflect[ing] [a] statutorily defined definition” misses the key point: The statute needlessly requires manufacturers to publicly parrot those terms, which concern an important public debate about drug pricing. *See* ECF 28-1 at 29 n.18; ECF 92 at 29–30, 33. The *BMS* decision relies on *Meese v. Keene*, 481 U.S. 465, 484 (1987), but that decision is inapposite because the statute at issue there allowed the pejorative *labeling* of certain material as “political propaganda” and, in contrast to the statute at issue here, did not compel anyone to use or embrace that term. If Congress had sought merely to regulate conduct through the Program, it could have done so without grafting an unnecessary speech requirement onto the price-regulation framework. *See* ECF 92 at 32–33.

Third, even if Boehringer’s participation in the Program were voluntary, that would not dispose of its unconstitutional conditions claim. The unconstitutional conditions doctrine limits the Government’s ability to condition “discretionary benefit[s]” on waivers of constitutional rights, ECF 92 at 36, meaning that a program is not exempt from scrutiny merely because it is voluntary. The *BMS* court’s single-paragraph analysis fails to account for that point: It erroneously concludes that the Program does not impose unconstitutional conditions in part because participation is, in the court’s view, voluntary.

Accordingly, and for the reasons given in Boehringer’s briefs, the Program violates the Constitution, and this Court should not follow the *BMS* court’s flawed reasoning.

Respectfully submitted,

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