IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION AT DAYTON

DAYTON AREA CHAMBER OF COMMERCE, et al.,

Plaintiffs,

v.

XAVIER BECERRA, et al.,

Defendants.

No. 3:23-cv-00156-MJN-PBS

Judge Michael J. Newman

Magistrate Judge Peter B. Silvain, Jr.

PLAINTIFFS' RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL <u>AUTHORITY</u>

The April 29 opinion of the district court in *Bristol Myers Squibb Co. v. Becerra*, No. 23-cv-3335 (D.N.J) ("*BMS*"), and *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 23-cv-3818 (D.N.J)., should have no bearing on this Court's decision in this case. *See* Dkt. 97 (Defendants' notice of supplemental authority regarding *BMS/Janssen*); Dkt. 97-1 (*BMS/Janssen* slip op. ("Op.")). The *BMS* and *Janssen* cases, which are substantively identical to each other, have little overlap with the claims raised in Plaintiffs' suit, and the district court's opinion does not grapple with key issues and arguments presented here.

First, the only "Fifth Amendment challenge" (Dkt. 97 at 1) that BMS and Janssen raised was a *Takings Clause* claim. Although the government obscures the contrast with this case by referring to that claim generically as a "Fifth Amendment" claim, *id.*, Plaintiffs here did not raise a Takings Clause claim; Plaintiffs raised a distinct claim under the *Due Process Clause*. Unlike the Takings Clause claim in *BMS* and *Janssen*, which alleged a physical taking of property, Plaintiffs' due process claim challenges the lack of *procedural* safeguards for price-setting, such as judicial review and statutory standards, under precedents such as *Mathews v. Eldridge*, 424

U.S. 319 (1976), and *Michigan Bell Telephone Co. v. Engler*, 257 F.3d 587 (6th Cir. 2001). Not surprisingly, given the lack of a due process challenge in *BMS* and *Janssen*, the opinion there did not address *Eldridge*, *Michigan Bell*, or other important due process precedents.

Second, BMS and Janssen did not challenge the constitutionality of the statute under the Constitution's separation of powers, the Excessive Fines Clause, or Congress's enumerated powers. The opinion thus does not address any of those claims raised by Plaintiffs here.

Third, although BMS and Janssen raised a First Amendment challenge, the opinion did not seriously engage with the argument that requiring manufacturers to use terms such as "agreement" and "maximum fair price" is compelled speech that is unnecessary to the operation of the IRA's price controls. The opinion asserted that the IRA "agreements and negotiations" are "incidental mechanisms the government is using to set those prices," Op. 22, without explaining why Congress needed to disguise price controls in the form of purported "agreements and negotiations" in the first place or how terminology such as "maximum fair price"—which forces manufacturers to mouth the government's talking points—was merely "incidental" to (i.e., a natural byproduct of) government price-setting. As Plaintiffs here have explained, the reality is that the IRA is "more than a mine-run price regulation" because it combines price controls with unnecessary speech controls. Dkt. 90 at 53 (quoting Expressions Hair Design v. Schneiderman, 581 U.S. 37, 47-48 (2017)). Furthermore, while the court emphasized that "the terms that [BMS and Janssen] object to are statutory terms of art," Op. 23, Plaintiffs here have explained that "the statutory definition" of a loaded term "cannot save" a compelled-speech requirement; otherwise, there would "be no end to the government's ability to skew public debate by forcing companies to use the government's preferred language." Dkt. 90 at 54 (quoting Nat'l Ass'n of Mfrs. v. SEC, 800 F.3d 518, 529-30 (D.C. Cir. 2015)). And the BMS/Janssen court did not address Plaintiffs'

argument here that, under *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205 (2013), the IRA "impermissibly seek[s] to regulate speech 'outside the contours' of the price-control program." Dkt. 90 at 55 (quoting *Open Soc'y*, 570 U.S. at 214–15); Dkt. 64 at 47–48.

Finally, the BMS/Janssen opinion did not meaningfully grapple with the arguments that the program is coercive or violates the unconstitutional conditions doctrine. Notably, the opinion does not even mention National Federation of Independent Business v. Sebelius, 567 U.S. 519 (2012) (NFIB). In likening the IRA's revolutionary new price-control program to ordinary "Medicare reimbursement limits," Op. 17, the opinion ignored NFIB's distinction between routine amendments to a federal healthcare program that do not change its fundamental nature and laws that "transform" the program so much as to create "in reality a new program," Dkt. 90 at 3, 41 (quoting NFIB, 567 U.S. at 581–85). As Judge Elrod of the Fifth Circuit recently observed at oral argument in Nat'l Infusion Ctr. Ass'n v. Becerra: "This is not a challenge to Medicare reimbursement, this is a challenge to a novel, unprecedented price-setting program in an industry [where] the government is the 800-pound gorilla." Oral Argument at 21:35-21:54, No. 24-50180 (5th Cir. May 1, 2024). Moreover, the BMS/Janssen opinion simply accepted the government's view that manufacturers can bypass the 11-to-23-month statutory period for a withdrawal to take effect, without analyzing whether CMS's guidance can be reconciled with the law. Op. 5 n.8; see Dkt. 90 at 49–50.

In sum, the BMS/Janssen opinion should have no effect on this Court's decision.

Dated: May 7, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 7, 2024, a true and correct copy of the foregoing Plaintiffs' Response to Defendants' Notice of Supplemental Authority was electronically filed with the Clerk of Court using the CM/ECF system which will send notification to all counsel of record.

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