# United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
**FILED**
April 9, 2026
Lyle W. Cayce
Clerk

No. 24-60340

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

*Plaintiff—Appellant*,

*versus*

LYNN FITCH, *in her official capacity as Attorney General of Mississippi*,

*Defendant—Appellee*.

Appeal from the United States District Court
for the Southern District of Mississippi
USDC No. 1:24-CV-160

Before KING, HO, and RAMIREZ, *Circuit Judges*.

PER CURIAM:[*]

Pharmaceutical Research and Manufacturers of America ("PhRMA") appeals the denial of its motion to preliminarily enjoin the enforcement of a state law governing the distribution of drugs that are discounted under a federal program. It contends that the state law is

[*] This opinion is not designated for publication. *See* 5TH CIR. R. 47.5.

preempted by federal law, unconstitutionally regulates out-of-state conduct, and is unconstitutionally vague. We AFFIRM.

## I

PhRMA represents biopharmaceutical research companies across the country and serves as the industry's principal policy advocate. Many of its members participate in Section 340B of the Public Health Service Act. Section 340B requires drug manufacturers to offer covered outpatient drugs at discounted prices to specified "covered entities," such as eligible nonprofit and public hospitals, community health centers, and clinics. 42 U.S.C. §§ 256b(a)(1), (a)(4). The Health Resources and Services Administration, which administers the Section 340B program, has interpreted the statute to permit covered entities to dispense 340B priced drugs to their patients through pharmacies with which they contract. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549, 43549 (Aug. 23, 1996); Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010). The statute prohibits covered entities from diverting discounted drugs by reselling or transferring them to nonpatients and from obtaining duplicate discounts through receipt of both Section 340B discounts and Medicaid rebates for the same drug. 42 U.S.C. §§ 256b(a)(5), (b)(2). To enforce those restrictions, manufacturers may audit covered entities' records to verify compliance and may seek prescription claims data from covered entities in connection with those audits. *Id.* § 256b(a)(5)(c).

Many participating drug manufacturers adopted policies restricting covered entities' use of contract pharmacies to dispense 340B priced drugs based on concerns that the arrangements create opportunities for abuse of the Section 340B program and impose significant costs on drug

manufacturers. In response, several states, including Mississippi, enacted laws regulating drug manufacturers' treatment of contract pharmacies.

Mississippi's statute, H.B. 728, prohibits drug manufacturers from "deny[ing], restrict[ing], prohibit[ing], or otherwise interfer[ing] with, either directly or indirectly, the acquisition . . . or delivery of" 340B priced drugs to contract pharmacies. MISS. CODE ANN. § 41-149-7(1) (2024). It also bars manufacturers from "interfer[ing] with a pharmacy contracted with a 340B entity." *Id.* § 41-149-7(2). A violation of H.B. 728 is considered a violation of the Mississippi Consumer Protection Act, MISS. CODE ANN. § 75-24-1 *et seq.* (2025), subject to its remedies and penalties, including civil and criminal penalties for knowing and willful violations. *See id.* §§ 75-24-9, -11, -19, -20.

PhRMA sued the Attorney General of Mississippi for declaratory and injunctive relief and sought a preliminary injunction against the enforcement of H.B. 728 on grounds that it was preempted by federal law, violated the Constitution's bar on regulating out-of-state commerce, and was unconstitutionally vague. The district court found that PhRMA had not shown a substantial likelihood of success on the merits of its claims and denied the motion for a preliminary injunction. PhRMA appealed.

## II

We review the denial of a preliminary injunction for abuse of discretion, reviewing underlying legal determinations de novo and factual findings for clear error. *Anibowei v. Morgan*, 70 F.4th 898, 902 (5th Cir. 2023); *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 642 (5th Cir. 2025).

A party seeking a preliminary injunction must establish:

> (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied

> outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.

*AbbVie*, 152 F.4th at 642 (quoting *Jones v. Tex. Dep't of Crim. Just.*, 880 F.3d 756, 759 (5th Cir. 2018)). When the government is a party, factors three and four merge. *Id.*

## III

PhRMA initially argues that because H.B. 728 "refashions" the scope of Section 340B, the district court erred in finding that it failed to show a likelihood of success on the merits of its claim that under the Supremacy Clause, H.B. 728 is preempted by federal law.

The Supremacy Clause provides that the laws of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. "Congress may implicitly preempt state law in two ways: field preemption and conflict preemption." *AbbVie*, 152 F.4th at 645. Field preemption occurs when Congress's intent to exclusively occupy a field can be inferred from pervasive federal regulation or a dominant federal interest. *Arizona v. United States*, 567 U.S. 387, 399 (2012); *Janvey v. Democratic Senatorial Campaign Comm., Inc.*, 712 F.3d 185, 200 (5th Cir. 2013). Conflict preemption occurs when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona*, 567 U.S. at 399. In areas traditionally regulated by the states, courts apply a presumption against preemption, requiring a clear and manifest congressional intent to displace state law. *Deanda v. Becerra*, 96 F.4th 750, 761 (5th Cir. 2024).

PhRMA contends that the district court erred by finding that H.B. 728 is not field preempted by federal law because Congress, in its view,

intended Section 340B to occupy the entire field of the program's administration and drug distribution. We recently rejected a substantially similar pre-enforcement preemption challenge to H.B. 728 in *AbbVie*. *AbbVie* explained that Section 340B is a drug pricing program that regulates costs, eligibility, and compliance; it does *not* govern "the distribution of [340B priced] drugs to patients and the role of pharmacies" in that process. 152 F.4th at 647; *see also AbbVie, Inc. v. Murrill*, 166 F.4th 528, 539 (5th Cir. 2026) (applying *AbbVie* to a materially indistinguishable Louisiana law and finding that it was not field preempted by Section 340B). H.B. 728, by contrast, regulates distribution-related functions that Section 340B leaves unaddressed and, therefore, remains subject to state regulation. *AbbVie*, 152 F.4th at 646.

*AbbVie* also applied the presumption against preemption because drug distribution and pharmacy operations fall within traditional state police powers—public health and consumer protection—and Congress included no indication in Section 340B that it meant to displace state authority in those areas. *Id.* at 646–47. The presumption against preemption reinforces the finding that H.B. 728 is not field preempted. *Id.*

Next, PhRMA argues that the district court erred by finding that H.B. 728 is not conflict preempted by federal law because it interferes with Section 340B's requirements. Its arguments rest on the premise that Section 340B governs manufacturers' obligations regarding contract pharmacies, compliance mechanisms, and enforcement. But *AbbVie* rejected that premise, explaining that Section 340B regulates drug pricing and requires manufacturers to "offer" discounted drugs to covered entities. *Id.* at 647. H.B. 728, instead, regulates the delivery of those drugs to patients and pharmacies' role in their distribution. *Id.* Because H.B. 728 does not change manufacturers' obligations under Section 340B, it does not interfere with Section 340B's compliance or enforcement scheme. *Id.* at 647–48. *AbbVie*,

therefore, held that H.B. 728 does not stand as an obstacle to Section 340B's objectives. *Id.* at 647.

PhRMA attempts to distinguish *AbbVie*, contending that it did not address its argument "about how the . . . [Section] 340B program addresses the obligations of manufacturers to provide 340B-priced drugs to 'contract pharmacies.'" It argues that H.B. 728 conflicts with federal law because it compels manufacturers to make additional sales beyond what Section 340B requires. But *AbbVie* squarely held that H.B. 728 "does not compel manufacturers to 'offer' discounted drugs to contract pharmacies"; it only requires them to allow covered entities to *receive* 340B priced drugs through the pharmacies they use to distribute drugs. 152 F.4th at 647 (citation modified). Because H.B. 728 does not impose additional requirements under Section 340B, it does not conflict with federal law. *AbbVie* therefore controls, and we are bound by that holding under our rule of orderliness. *See Murrill*, 166 F.4th at 539 (finding that "[*AbbVie*] controls" the conflict preemption analysis for a materially identical Louisiana statute); *Jacobs v. Nat'l Drug Intel. Ctr.*, 548 F.3d 375, 378 (5th Cir. 2008) ("It is a well-settled Fifth Circuit rule of orderliness that one panel of our court may not overturn another panel's decision, absent an intervening change in the law, such as by a statutory amendment, or the Supreme Court, or our *en banc* court.").

Because PhRMA failed to show that H.B. 728 is neither field preempted nor conflict preempted by federal law, the district court did not err by finding that it failed to show a likelihood of success on the merits of its preemption claim. *See AbbVie*, 152 F.4th at 648.

## IV

PhRMA next argues that because H.B. 728 seeks to regulate conduct outside of its borders, the district court erred in finding that it failed to show

a likelihood of success on the merits of its claim that H.B. 728 violates the Commerce Clause.[1]

The Commerce Clause prohibits "the application of a state statute to commerce that takes place wholly outside of the State's borders." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 640 (1982)). The Commerce Clause's "critical inquiry" is whether the statute's practical effect is to control conduct outside the state, "regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id.*

But under Mississippi law, the Legislature's intent determines the practical effect. In interpreting Mississippi law, we start from the presumption that statutes "operat[e] only as to persons or things within" the Mississippi Legislature's "territorial jurisdiction." *Tattis v. Karthans*, 215 So. 2d 685, 689–90 (Miss. 1968) (quoting 50 AM. JUR. *Statutes* § 487 (1944)). And that presumption is overcome only if "the intention to have a statute operate beyond the limits of the state . . . is clearly expressed or indicated . . . ." *Id.*

Here, the statute evinces no such intent. It provides that drug manufacturers "shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity." MISS. CODE ANN. § 41-149-7(1). Nothing in the text extends H.B. 728 beyond Mississippi's borders or indicates that the Legislature intended it to apply extraterritorially. And PhRMA's contention that H.B. 728 applies

[1] Although PhRMA also alleged a violation of the Due Process Clause, it has forfeited this argument by failing to adequately brief it. *Rollins v. Home Depot USA*, 8 F.4th 393, 397 (5th Cir. 2021) ("A party forfeits an argument . . . by failing to adequately brief the argument on appeal.").

extraterritorially because the statutory definition of "pharmacy" contains no explicit geographic limitation flips this presumption on its head and does little to rebut it. Consequently, Mississippi's presumption against extraterritorial effect stands, and the Commerce Clause does not bar enforcement of H.B. 728.

Because PhRMA fails to show that H.B. 728 regulates out-of-state commerce, the district court did not err in finding that it failed to show a likelihood of success on the merits.

## V

Finally, PhRMA argues that H.B. 728 is unconstitutionally vague because it fails to provide manufacturers notice of prohibited conduct.

Under the Due Process Clause, the void-for-vagueness doctrine "bars enforcement of a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application." *United States v. Lanier*, 520 U.S. 259, 266 (1997) (citation modified). A law is unconstitutionally vague only when it fails to specify a standard of conduct "at all," and in the civil context the threshold is especially high: "the statute must be so vague and indefinite as really to be no rule at all." *Murrill*, 166 F.4th at 546 (citation modified).

As noted, H.B. 728 prohibits a manufacturer from "deny[ing], restrict[ing], prohibit[ing], or otherwise interfere[ing] with" the acquisition or delivery of 340B priced drugs to a contract pharmacy. MISS. CODE ANN. § 41-149-7(1). It also bars manufacturers from "interfer[ing] with a pharmacy contracted with a 340B entity." *Id.* § 41-149-7(2).

PhRMA contends that the scope of the term "interfere" is so unclear that it *could* chill lawful conduct by "prohibiting manufacturers from even requesting information" necessary to conduct compliance audits permitted

under Section 340B.[2] We recently rejected a similar vagueness challenge to an identically worded Louisiana statute in *Murrill*. Applying the canon that "a word is known by its associates," *Murrill* explained that "interfere," read in context with its neighboring terms—"deny, restrict, [and] prohibit"—"targets conduct that obstructs or impedes the acquisition or delivery of 340B drugs to contract pharmacies—not routine communications or lawful auditing practices." 166 F.4th at 547 (citation modified). Because *Murrill* has already interpreted "interfere" to reach only obstructive conduct in the context of the very same language as H.B. 728, that interpretation controls. *Jacobs*, 548 F.3d at 378. PhRMA's vagueness challenge is therefore foreclosed, and the district court did not err in finding that it failed to show a likelihood of success on the merits.

## VI

Because PhRMA has failed to show a likelihood of success on the merits of all its claims, the district court did not abuse its discretion in denying a preliminary injunction. *See AbbVie*, 152 F.4th at 648. We AFFIRM.

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[2] PhRMA asserts in passing that the vagueness doctrine requires heightened clarity because H.B. 728 "reaches speech" and imposes criminal penalties. But PhRMA does not develop a First Amendment vagueness argument, and H.B. 728 regulates conduct, not protected expression. *AbbVie*, 152 F.4th at 647–48. Although H.B. 728 carries criminal penalties, liability attaches only for knowing and willful violations, thereby limiting liability to manufacturers who act with awareness of the prohibited conduct, which in turn mitigates potential notice concerns. *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 499 (1982) (explaining that a scienter requirement can mitigate vagueness, especially with respect to the notice).