United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
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Lyle W. Cayce
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No. 24-60375

ABBVIE, INCORPORATED, *a Delaware corporation*; ALLERGAN, INCORPORATED, *a Delaware corporation*; DURATA THERAPEUTICS, INCORPORATED, *a Delaware corporation*; ABBVIE PRODUCTS, L.L.C., *a Georgia limited liability company*; APTALIS PHARMA US, INCORPORATED, *a Delaware corporation*; PHARMACYCLICS, L.L.C., *a Delaware limited liability company*; ALLERGAN SALES, L.L.C., *a Delaware limited liability company*,

Plaintiffs—Appellants,

versus

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

Defendant—Appellee.

Appeal from the United States District Court
for the Southern District of Mississippi
USDC No. 1:24-CV-184

Before ELROD, *Chief Judge*, and CLEMENT and RAMIREZ, *Circuit Judges*.

PER CURIAM:[*]

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

Under the federal Section 340B program, drug manufacturers that participate in Medicaid and Medicare Part B must offer certain drugs to healthcare providers ("covered entities") that serve uninsured and low-income individuals at discounted prices. In recent years, drug manufacturers have enacted policies that prevent covered entities from contracting with third-party commercial pharmacies ("contract pharmacies") to distribute these discounted drugs to patients, allegedly to prevent contract pharmacies from improperly distributing the drugs to consumers for profit. But in 2024, to combat such policies, Mississippi enacted H.B. 728, which prohibits drug manufacturers from interfering with covered entities' distribution of Section 340B drugs via contract pharmacies.

Appellants, a group of drug manufacturers that participate in the 340B program (collectively, "AbbVie"), sued the Attorney General of Mississippi, alleging takings and preemption claims and seeking declaratory and injunctive relief from H.B. 728. The district court denied AbbVie's motion for a preliminary injunction.

If H.B. 728 works the way that AbbVie alleges it does—allowing covered entities and contract pharmacies to flout Section 340B's diversion ban by improperly reselling discounted Section 340B drugs—it would undoubtedly be a problematic statute. But on the specific claims and sparse record before us, we cannot say that injunctive relief is appropriate. The district court's denial of a preliminary injunction on this record was not erroneous, so we AFFIRM.

I

A

In 1992, Congress created the Section 340B program to ensure that uninsured and low-income individuals can access the medications they need and to ensure that medical providers serving these individuals receive crucial

subsidies. *See* 42 U.S.C. § 256(b); *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 115 (2011). Section 340B requires drug manufacturers, as a condition of coverage of their products under Medicaid and Medicare Part B, to agree to offer certain drugs to "covered entities" at no more than the statutorily-set "ceiling price." 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1), (5). The list of covered entities includes, *inter alia*, federal- or state-funded hospitals and community health centers that primarily serve low-income patients. *See id.* § 256b(a)(4).

The 340B program places several key restrictions on covered entities. First, it bars "duplicate discounts or rebates," forbidding covered entities from seeking both the 340B discount and a Medicaid rebate on the same drug. *Id.* § 256b(a)(5)(A). Second, it bars "diversion," providing that a covered entity "shall not resell or otherwise transfer" a discounted drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Third, it requires covered entities to permit the Secretary of Health & Human Services ("HHS") and drug manufacturers to "audit" their records to assess compliance with the duplicate-discount and diversion bans. *Id.* § 256b(a)(5)(C). And fourth, it provides that a covered entity that violates the duplicate-discount or diversion bans "shall be liable" to the drug manufacturer for the amount improperly received. *Id.* § 256b(a)(5)(D).

B

In 1996, four years after Section 340B's enactment, the Health Resources & Services Administration ("HRSA") noted the statute's "silen[ce] as to permissible drug distribution systems" to patients. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549, 43549 (Aug. 23, 1996). HRSA therefore issued guidance permitting covered entities lacking an in-house dispensing pharmacy to contract with a single third-party commercial

pharmacy to receive and dispense Section 340B drugs to their patients, so long as they abided by Section 340B's requirements and its duplicate-discount and diversion bans. *Id.* at 43550–55.

But in 2010, HRSA changed course, issuing new guidance permitting all covered entities—even those with an in-house dispensing pharmacy—to contract with an unlimited number of outside pharmacies to distribute Section 340B drugs to their patients. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010). Covered entities were quick to take advantage of this, and the number of contract pharmacies partnered with covered entities increased from 1,300 to 23,000 by 2019. *See* U.S. Gov't Accountability Off., GAO-20-212, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement 2 (2020). In these partnerships, "the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy," and the contract pharmacy then takes physical possession of but not title to the drugs. *Advisory Op. 20-06 on Contract Pharmacies under the 340B Program*, 2020 WL 11422965, at *1 (Dec. 30, 2020).[1]

By 2020, AbbVie and other drug manufacturers sought to combat the proliferation of partnerships between covered entities and contract pharmacies, which they believed "le[d] to unlawful diversion and duplicate discounts." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 458 (D.C. Cir. 2024). Drug manufacturers therefore began to adopt policies that restricted covered entities' ability to partner with contract pharmacies. AbbVie's

[1] This is how contract pharmacy partnerships are supposed to work, according to HHS. AbbVie asserts that things work differently in practice, averring that, in reality, the contract pharmacy often takes title to the drugs.

contract-pharmacy policy, which essentially follows HRSA's 1996 guidance, permits a covered entity lacking an in-house pharmacy to distribute its Section 340B drugs through only one contract pharmacy, located within 40 miles of the covered entity.

HHS acted quickly to prohibit drug manufacturers from imposing these restrictive contract-pharmacy policies, issuing an advisory opinion in December 2020 stating that, "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." *Advisory Op. 20-06*, 2020 WL 11422965, at *1. Drug manufacturers took HHS and HRSA to court to challenge this advisory opinion, and several circuits upheld the drug manufacturers' contract-pharmacy policies as consistent with Section 340B. *See Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 704 (3d Cir. 2023); *Novartis*, 102 F.4th at 460. HHS ultimately withdrew the advisory opinion.

C

Soon after, several states passed laws to protect covered entities' partnerships with contract pharmacies, attempting to do by statute what HHS had done in its advisory opinion.

Mississippi enacted H.B. 728, which states 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 at 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity," nor can they "interfere with a pharmacy contracted with" a covered entity. Miss. H.B. 728 § 4(1)–(2) (2024). H.B. 728 defines a "340B drug" as "a drug that has been subject to any offer for reduced prices by a

manufacturer pursuant to 42 U.S.C. § 256b and is purchased by a covered entity as defined in 42 U.S.C. § 256b(a)(4)."

A manufacturer that violates H.B. 728 is subject to statutory penalties for unlawful business practices under the Mississippi Consumer Protection Act, MISS. CODE ANN. § 75-24-1 *et seq.*, including injunctions, civil penalties, criminal penalties, and restitution or revocation of licenses or certificates to "engage in business" in Mississippi. *Id.* §§ 75-24-9, -11, -19, -20.

D

In June 2024, AbbVie, a group of drug manufacturers that participate in the 340B program, sued the Attorney General of Mississippi, challenging H.B. 728 as unconstitutional and seeking declaratory judgment and injunctive relief.

Twelve days before H.B. 728 took effect, AbbVie moved for a preliminary injunction. In its motion, AbbVie contended that: (1) H.B. 728 effectuates an unconstitutional taking of property because it compels AbbVie to transfer its drugs at significant discounts to private, for-profit pharmacies, rather than for a "public use"; and (2) H.B. 728 is preempted by federal law because it expands manufacturers' obligations under the 340B program and brings its own enforcement scheme to bear. The district court denied AbbVie's motion, concluding that AbbVie had not shown a substantial likelihood of success on the merits of its claims and therefore was not entitled to preliminary injunctive relief. AbbVie timely appealed.

II

"The decision to grant or deny a preliminary injunction lies within the discretion of the district court and may be reversed on appeal only by a showing of abuse of discretion." *Anibowei v. Morgan*, 70 F.4th 898, 902 (5th

Cir. 2023), *cert. denied sub nom. Anibowei v. Mayorkas*, 144 S. Ct. 551 (2024). "Factual findings are reviewed for clear error, while legal conclusions are reviewed de novo." *Jones v. Tex. Dep't of Crim. Just.*, 880 F.3d 756, 759 (5th Cir. 2018).

"[A] preliminary injunction is an extraordinary and drastic remedy which should not be granted unless the movant clearly carries the burden of persuasion." *Anibowei*, 70 F.4th at 902. To obtain a preliminary injunction, the movant 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.

Jones, 880 F.3d at 759 (quoting *Byrum v. Landreth*, 566 F.3d 442, 445 (5th Cir. 2009)). The third and fourth factors "merge when the government is a party." *Mock v. Garland*, 75 F.4th 563, 577 (5th Cir. 2023).

III

We turn first to AbbVie's takings claim. AbbVie asserts that H.B. 728 effectuates a physical taking, or, in the alternative, a regulatory taking, for private use and without just compensation. We consider AbbVie's physical takings and regulatory takings arguments in turn.

Although it is possible that H.B. 728 could, as AbbVie asserts, allow covered entities and contract pharmacies to engage in illicit behavior that violates Section 340B, we conclude that, to the extent AbbVie has a

compensable property interest in the drugs regulated by H.B. 728,[2] the district court did not abuse its discretion in denying preliminary injunctive relief as to AbbVie's takings claim, because AbbVie has not shown a substantial likelihood of success on the merits of this claim.

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[2] We "understand takings analysis to be centered on the deprivation of a former owner's property interest, and not on the accretion of that interest to the government." *United States v. 0.073 Acres of Land*, 705 F.3d 540, 544 (5th Cir. 2013). Thus, for a party to have a viable takings claim, it must show that it had a "compensable property interest" in the property allegedly taken at the time of the alleged taking. *Id.* at 544–45. State law governs "what is a property interest compensable under the Fifth Amendment." *United States v. 131.68 Acres of Land*, 695 F.2d 872, 875 (5th Cir. 1983). Here, it is unclear whether AbbVie has a compensable property interest in all drugs regulated by H.B. 728. The statute defines a "340B" drug as "a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and *is purchased by a covered entity* as defined in 42 U.S.C. § 256b(a)(4)." H.B. 728 § 2(a) (emphasis added). The language "is purchased by" could plausibly refer to drugs both before and after they are purchased by a covered entity.

To the extent H.B. 728 regulates drugs pre-purchase, AbbVie has a compensable property interest in the drugs, because it still owns them. *See State v. Murphy*, 202 So.3d 1243, 1251 (Miss. 2016) (en banc) (Mississippi Constitution protects private property). But to the extent H.B. 728 regulates drugs post-purchase, AbbVie may not have a compensable property interest in the drugs, because AbbVie is no longer the drugs' owner after the point of sale. As AbbVie describes, when a covered entity partners with a contract pharmacy, orders for Section 340B drugs are placed with AbbVie using the covered entity's account. After the Section 340B drugs are purchased, AbbVie ships them to the contract pharmacy. *Advisory Op. 20-06*, 2020 WL 11422965, at *1. While AbbVie still has physical custody of the post-purchase drugs until it ships them, we have found no indication that Mississippi law recognizes a compensable property interest in goods that a party temporarily possesses on the owner's behalf. To the contrary, Mississippi law might consider AbbVie a bailee with an obligation to transfer the drugs as directed by the covered entity as bailor. *See* MISS. CODE ANN. § 75-7-403 (West 2025); *Baggett v. McCormack*, 19 So. 89, 90 (Miss. 1896) (recognizing that a bailee has "no legal interest in [property], as against his bailor," but instead only a possessory interest "in the custody and care of the property" that accords with the bailor's rights as owner). Consequently, it may be the case that because AbbVie does not own the Section 340B drugs after the point of sale, it has no compensable property interest in at least some of the drugs regulated by H.B. 728. We need not decide this question, though, because we conclude that AbbVie's takings claim fails regardless.

A

The government effectuates a physical taking when it "physically takes possession of an interest in property for some public purpose." *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 322 (2002). Examples of physical takings include when the government "uses its power of eminent domain to formally condemn property," "physically takes possession of property without acquiring title to it," or "occupies property"—whether on its own behalf or for the benefit of a third party. *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147–48 (2021).

AbbVie has not shown that H.B. 728 effectuates a physical taking of AbbVie's property. The record indicates that H.B. 728 does not impose on drug manufacturers a positive obligation to directly transfer or sell their drugs to anyone. Nor does it require them to sell larger quantities of their drugs at discounted prices than Section 340B requires and thereby deprive them of sales at full market price. Under H.B. 728, AbbVie still receives payment of the full discounted amounts to which it is entitled under Section 340B. H.B. 728 simply imposes on drug manufacturers a negative obligation of non-interference with covered entities' arrangements with contract pharmacies, by preventing them from refusing to sell Section 340B drugs to covered entities that have arrangements with contract pharmacies and from restricting what covered entities can do with Section 340B drugs after they have purchased them.

Because AbbVie has not shown that H.B. 728 effectuates a physical taking, AbbVie cannot meet its burden of showing a substantial likelihood of success on the merits of this argument.

B

The government effectuates a regulatory taking when it "goes too far" in "impos[ing] regulations that restrict an owner's ability to use his own

property." *Cedar Point Nursery*, 594 U.S. at 148 (first quoting *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)). To determine whether a law effectuates a regulatory taking, courts apply "the flexible test" announced in *Penn Central Transportation Company v. City of New York*, 438 U.S. 104 (1978), which requires "balancing factors such as the economic impact of the regulation, its interference with reasonable investment-backed expectations, and the character of the government action." *Cedar Point Nursery*, 594 U.S. at 148. This inquiry "necessarily entails complex factual assessments of the purposes and economic effects of government actions." *Yee v. City of Escondido*, 503 U.S. 519, 523 (1992).

To the extent the regulatory takings doctrine applies,[3] AbbVie has not shown that H.B. 728 effectuates a regulatory taking under the *Penn Central* test. As to the first factor: H.B. 728 may have an economic impact on drug manufacturers, because it could increase the number of drugs for which they must provide discounts and therefore cut into their profits. AbbVie asserts that it will "face the threat of millions of dollars in forced unnecessary discounts each year." But for most drugs, manufacturers will still receive a large percentage of the market price. *See Sanofi Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F.Supp.3d 129, 208 (D.N.J. 2021) ("[T]he average discount rate appears to be between 25 and 50 percent . . . ."), *aff'd in part, rev'd in part on other grounds*, 58 F.4th 696 (3d Cir. 2023).

As to the second *Penn Central* factor: H.B. 728 does not significantly interfere with drug manufacturers' reasonable investment-backed expectations. As the district court remarked, when Congress enacted

[3] AbbVie asserts that the regulatory takings doctrine does not apply in this case but maintains that if it does apply, H.B. 728 effectuates a regulatory taking and AbbVie still prevails. The district court applied the doctrine and concluded that H.B. 728 does not effectuate a regulatory taking.

Section 340B, "only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500)," meaning that the potential for dispensation of Section 340B drugs by contract pharmacies was foreseeable. Notice Regarding Section 602, 61 Fed. Reg. at 43550. And while HRSA's August 1996 guidance provided a "guideline[]" of one contract pharmacy per covered entity without an in-house pharmacy, that guidance nonetheless appears to contemplate that state law might protect covered entities' "right" to purchase drugs at 340B prices and have them dispensed at multiple pharmacies. *See id.* ("*Comment:* As a matter of State [agency] law, [covered] entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. . . . *Response:* We agree.").

As to the third *Penn Central* factor: the character of the government action in H.B. 728 weighs in the state's favor. H.B. 728 was not "enacted solely for the benefit of private parties," but rather furthers "important public interests," like expanding needy patients' access to care and giving covered entities better ability to expand and improve their services. *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 485–86 (1987). Record evidence shows that restrictive contract-pharmacy policies detrimentally affect patient access and provider offerings.

On balance, the *Penn Central* factors weigh heavily in the state's favor, causing us to conclude that AbbVie has not shown that H.B. 728 effectuates a regulatory taking and that AbbVie therefore has not met its burden of showing a substantial likelihood of success on the merits of this argument.

* * *

In sum, because AbbVie has not met its burden of showing a substantial likelihood of success on the merits of its takings claim, whether on a physical takings or regulatory takings theory, we conclude that the

district court did not abuse its discretion in denying AbbVie preliminary injunctive relief on this claim.[4]

IV

We turn next to AbbVie's preemption claim. AbbVie asserts that federal law implicitly preempts H.B. 728 under both field preemption and conflict preemption theories. The district court disagreed and denied AbbVie's request for preliminary injunctive relief. We consider AbbVie's field preemption and conflict preemption arguments in turn.

Again, it could be the case that H.B. 728 permits illicit behavior that violates Section 340B. But we conclude, as the district court did, that there is insufficient evidence in the record to support this allegation. Accordingly, we hold that the district court did not abuse its discretion as to AbbVie's preemption claim, because AbbVie has not shown a substantial likelihood of success on the merits of this claim.

A

The Supremacy Clause provides that "the Laws of the United States which shall be made in Pursuance" of the Constitution are "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. Consequently, Congress may "pre-empt a state law, rule, or other state action" through federal legislation, either "through express language in a statute" or "implicitly." *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376–77 (2015).

[4] Because H.B. 728 effectuates neither a physical taking nor a regulatory taking, we need not consider the parties' additional arguments regarding whether any alleged taking is for a "public use" or whether the voluntary participation doctrine applies.

Congress may implicitly preempt state law in two ways: field preemption and conflict preemption.

"Deference to our federalism counsels a presumption that areas of law traditionally reserved to the states . . . are not to be disturbed absent the clear and manifest purpose of Congress." *In re Davis*, 170 F.3d 475, 481 (5th Cir. 1999) (en banc) (internal quotation marks omitted); *see Deanda v. Becerra*, 96 F.4th 750, 761 (5th Cir. 2024) (a "presumption against preemption" applies to "areas of law traditionally reserved to the states"). In keeping with this presumption, when there is doubt about preemption, the "tie goes to the state." *White Buffalo Ventures, LLC v. Univ. of Tex. at Austin*, 420 F.3d 366, 370 (5th Cir. 2005).

B

"[T]he States are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance." *Arizona v. United States*, 567 U.S. 387, 399 (2012). "The intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive . . . that Congress left no room for the States to supplement it' or where there is a 'federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Id.* (alterations in original) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *see Janvey v. Democratic Senatorial Campaign Comm., Inc.*, 712 F.3d 185, 200 (5th Cir. 2013).

Field preemption "should not be inferred, however, simply because the agency's regulations are comprehensive." *R.J. Reynolds Tobacco Co. v. Durham County*, 479 U.S. 130, 149 (1986). Just because "federal provisions [a]re sufficiently comprehensive to meet the need identified by Congress d[oes] not mean that States and localities [a]re barred from identifying

additional needs or imposing further requirements in the field." *Hillsborough County v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 717 (1985).

Here, there is no federal framework so pervasive that Congress left no room for state supplementation. Section 340B is a drug pricing program that "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities," *Astra*, 563 U.S. at 113; *see* 42 U.S.C. § 256(b), with the intent of supporting "services for low-income and rural communities," *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). Section 340B explicitly regulates several key matters: it caps the prices of covered drugs, 42 U.S.C. § 256b(a)(1), (a)(10); controls eligibility for "covered entity" status, *id.* § 256b(a)(4); prohibits covered entities from claiming duplicate discounts and engaging in diversion, *id.* § 256b(a)(5)(A)-(B); enforces compliance with its caps and bars, *id.* § 256b(a)(5)(D), (d)(1)-(3); and governs distribution of discounted drugs to covered entities by manufacturers and third-party wholesalers, *id.* § 256b(a)(8).

But Section 340B does not "provide a full set of standards governing" discounted drugs for needy patients. *Arizona*, 567 U.S. at 401. Notably, it regulates neither the distribution of drugs to patients nor the role of pharmacies in this distribution. *See* Notice Regarding Section 602, 61 Fed. Reg. at 43549–50 (noting "many gaps in the legislation" and that Section 340B "is silent as to permissible drug distribution systems"); *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1144 (8th Cir.) (noting "Congressional silence on pharmacies in the context of 340B"), *cert. denied*, 145 S. Ct. 768 (2024); *Novartis*, 102 F.4th at 460 (stating that Section 340B is "silent about delivery conditions"); *Sanofi Aventis*, 58 F.4th at 703 (noting that Section 340B "is silent about delivery" of drugs to patients and "[n]owhere . . . mention[s] contract pharmacies"). As the Third Circuit has pointed out, Congress "knew how to impose delivery-related requirements" and regulate distribution, because Section 340B does authorize distribution

of drugs by manufacturers and third-party wholesalers. *Sanofi Aventis*, 58 F.4th at 704. But Congress chose not to regulate distribution to patients, indicating that it did not intend to occupy the entire field in this area. As the Supreme Court has held, "matters left unaddressed" in an otherwise "comprehensive and detailed" federal regulatory scheme "are presumably left subject to the disposition provided by state law." *O'Melveny & Myers v. FDIC*, 512 U.S. 79, 85 (1994).

Next, there is no dominant federal interest in the area regulated by H.B. 728. H.B. 728 implicates two traditional general areas of state regulation and police power: public health and consumer protection. *See, e.g.*, *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 325 (2016) (noting "the State's traditional power to regulate in the area of public health"); *Castro v. Collecto, Inc.*, 634 F.3d 779, 784–85 (5th Cir. 2011) ("[S]tates have traditionally governed matters regarding contracts and consumer protections . . . ."). Although there are instances in which the Supreme Court has held that federal law preempts state law "even if the state law exercises a traditional state power," that is usually in cases in which a "principal and essential feature" of the federal law is replicated in the state law, indicating that it is a "fundamental area of [federal] regulation." *Gobeille*, 577 U.S. at 325–26.[5]

But we have recently reiterated that "[c]ourts should not infer field preemption in 'areas that have been traditionally occupied by the states,' in

[5] For instance, the Supreme Court and this court have recognized that there is a dominant federal interest in certain key areas of public health and consumer protection regulation. *See, e.g.*, *Gobeille*, 577 U.S. at 319–20 (noting that ERISA preempts state laws that have a "reference to" ERISA plans or an impermissible "connection with" ERISA plans); *Texas v. United States*, 945 F.3d 355, 369–71 (5th Cir. 2019) (noting the Affordable Care Act's displacement of certain state healthcare and consumer protection laws), *rev'd on other grounds sub nom. California v. Texas*, 593 U.S. 659 (2021).

which case congressional intent to preempt must be 'clear and manifest.'" *Nat'l Press Photographers Ass'n v. McCraw*, 90 F.4th 770, 796 (5th Cir.) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)), *cert. denied sub nom. Nat'l Press Photographers Ass'n v. Higgins*, 145 S. Ct. 140 (2024). Here, Congress has expressed no clear and manifest intent to preempt state laws regulating the distribution of drugs to patients and the role of pharmacies in such distribution. Accordingly, applying the presumption against field preemption, we conclude that H.B. 728 is not field preempted.

C

Conflict preemption applies when "compliance with both federal and state regulations is a physical impossibility" and when the challenged 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 (internal quotations omitted); *see Janvey*, 712 F.3d at 200. "What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). "'Conflict is imminent' when 'two separate remedies are brought to bear on the same activity.'" *Id.* at 380.

AbbVie raises the latter of the two conflict preemption scenarios, contending that H.B. 728 "stand[s] as an obstacle to" Congress's purposes and objectives under Section 340B, *Arizona*, 567 U.S. at 399, because it: (1) compels manufacturers to provide their drugs at Section 340B prices to entities other than those specifically enumerated in § 256b(a)(4); and (2) imposes civil and criminal penalties for noncompliance with its provisions.

AbbVie's first argument is simply incorrect. H.B. 728 does not expand Section 340B's list of covered entities to include contract

pharmacies. By its plain text, H.B. 728 requires drug manufacturers to give custody of discounted drugs to contract pharmacies only insofar as they have partnered with covered entities to distribute the drugs to patients. It does not compel manufacturers to "offer" discounted drugs to contract pharmacies in the way that Section 340B compels them to "offer" these drugs to covered entities.

AbbVie's second argument also fails because H.B. 728's enforcement scheme does not conflict with Section 340B's enforcement scheme. It is true that Congress made HHS the sole enforcer of Section 340B. *See Astra*, 563 U.S. at 120. But H.B. 728 does not intrude upon this authority because it does not impose penalties for violations of Section 340B, like failing to offer discounted drugs to covered entities or engaging in diversion. Instead, it imposes penalties when drug manufacturers violate H.B. 728 by interfering with the distribution of Section 340B drugs pursuant to covered entities' partnerships with contract pharmacies. H.B. 728's enforcement scheme therefore does not "concern[] the same subject matter" as Section 340B and cannot be said to conflict with it.

Regardless, as set out above, the presumption against preemption applies here because H.B. 728 regulates matters that have traditionally been the domain of the states. *See Deanda*, 96 F.4th at 761. Applying this presumption, we conclude that H.B. 728 is not conflict preempted.

* * *

Again, we recognize that H.B. 728 could, if AbbVie's allegations are true, have the effect of allowing covered entities and contract pharmacies to engage in illicit activities that flout Section 340B's diversion ban. But on the record before us, we conclude that the district court did not abuse its discretion in denying preliminary injunctive relief as to AbbVie's preemption

claim because AbbVie has not proffered sufficient evidence to show a substantial likelihood of success on the merits of this claim.

V

As we understand it, AbbVie's grievance is this: it believes that when covered entities are allowed to distribute Section 340B drugs via contract pharmacies, those contract pharmacies cause covered entities to place orders for larger quantities of discounted drugs than they are actually entitled to, and the contract pharmacies then improperly resell those discounted drugs in ways that increase their profits. AbbVie avers that H.B. 728 has the practical effect of allowing this type of illicit activity to occur.

AbbVie is essentially alleging that the real problem with H.B. 728 is not a *feature* of the law, but rather a *bug*. And on this record, we cannot say that this potential bug in H.B. 728 merits a preliminary injunction. Because AbbVie has not proffered the requisite facts as to either of its claims, the district court did not abuse its discretion in denying AbbVie preliminary injunctive relief. *See Jones*, 880 F.3d at 759.

AFFIRMED.

United States Court of Appeals

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MEMORANDUM TO COUNSEL OR PARTIES LISTED BELOW

Regarding: Fifth Circuit Statement on Petitions for Rehearing or Rehearing En Banc

No. 24-60375 AbbVie v. Fitch
USDC No. 1:24-CV-184

Enclosed is a copy of the court's decision. The court has entered judgment under Fed. R. App. P. 36. (However, the opinion may yet contain typographical or printing errors which are subject to correction.)

Fed. R. App. P. 39 through 41, and Fed. R. App. P. 39, 40, and 41 govern costs, rehearings, and mandates. **Fed. R. App. P. 40 require you to attach to your petition for panel rehearing or rehearing en banc an unmarked copy of the court's opinion or order.** Please read carefully the Internal Operating Procedures (IOP's) following Fed. R. App. P. 40 for a discussion of when a rehearing may be appropriate, the legal standards applied and sanctions which may be imposed if you make a nonmeritorious petition for rehearing en banc.

Direct Criminal Appeals. Fed. R. App. P. 41 provides that a motion for a stay of mandate under Fed. R. App. P. 41 will not be granted simply upon request. The petition must set forth good cause for a stay or clearly demonstrate that a substantial question will be presented to the Supreme Court. Otherwise, this court may deny the motion and issue the mandate immediately.

Pro Se Cases. If you were unsuccessful in the district court and/or on appeal, and are considering filing a petition for certiorari in the United States Supreme Court, you do not need to file a motion for stay of mandate under Fed. R. App. P. 41. The issuance of the mandate does not affect the time, or your right, to file with the Supreme Court.

Court Appointed Counsel. Court appointed counsel is responsible for filing petition(s) for rehearing(s) (panel and/or en banc) and writ(s) of certiorari to the U.S. Supreme Court, unless relieved of your obligation by court order. If it is your intention to file a motion to withdraw as counsel, you should notify your client promptly, **and advise them of the time limits for filing for rehearing and certiorari**. Additionally, you MUST confirm that this information was given to your client, within the body of your motion to withdraw as counsel.

The judgment entered provides that each party bear its own costs on appeal.

Sincerely,

LYLE W. CAYCE, Clerk

By:_____
Jasmine J. Forman, Deputy Clerk

Enclosure(s)

Ms. Margaret Dotzel
Mr. Lucas Henry Funk
Ms. Alyssa Howard
Mr. Carey Thompson Jones
Mr. Justin Lee Matheny
Mr. Matthew Scott Owen
Ms. Meredith Marie Pohl
Mr. William B. Schultz
Mr. Rex Morris Shannon III
Mr. William Lucien Smith Sr.
Mr. Scott G. Stewart