United States Court of Appeals for the Fifth Circuit

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

No. 24-30645

AbbVie, Incorporated; Allergan, Incorporated; Durata Therapeutics, Incorporated; AbbVie Products, L.L.C.; Aptalis Pharma US, Incorporated; Allergan Sales, L.L.C.; Pharmacyclics, L.L.C.,

Plaintiffs—Appellants,

versus

Liz Murrill, *in her official capacity as Attorney General of Louisiana*,

Defendant—Appellee,

Louisiana Primary Care Association,

Intervenor Defendant—Appellee,

CONSOLIDATED WITH

No. 24-30651

AstraZeneca Pharmaceuticals, L.P.,

Plaintiff—Appellant,

versus

LIZ MURRILL, *in her official capacity as Attorney General of the State of Louisiana*,

Defendant—Appellee,

LOUISIANA PRIMARY CARE ASSOCIATION,

Intervenor Defendant—Appellee,

CONSOLIDATED WITH

No. 24-30673

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff—Appellant,

versus

LIZ MURRILL, *in her official capacity as Attorney General of Louisiana*,

Defendant—Appellee,

LOUISIANA PRIMARY CARE ASSOCIATION,

Intervenor Defendant—Appellee.

Appeals from the United States District Court
for the Western District of Louisiana
USDC Nos. 6:23-CV-1307, 6:23-CV-1042,
6:23-CV-997

Before HIGGINSON, WILLETT, and ENGELHARDT, *Circuit Judges*.

DON R. WILLETT, *Circuit Judge*:

When Congress created the Section 340B Drug Pricing Program, it struck a straightforward bargain: drug manufacturers that choose to participate in Medicaid must provide discounted drugs to certain "covered entities"—most often clinics and hospitals that serve low-income and rural patients.[1] The goal was simple: stretch scarce healthcare dollars and expand access to essential medications for vulnerable communities.

In practice, many covered entities lack the resources to operate in-house pharmacies. To bridge that gap—particularly in rural and underserved areas—they purchase discounted drugs and partner with independent contract pharmacies to dispense them. Some manufacturers, however, have bristled at that arrangement, characterizing it as an "arbitrage opportunity" for pharmacies rather than a lifeline for patients. Acting on that view, certain manufacturers adopted policies restricting covered entities' use of contract pharmacies.

Louisiana responded as other states have in matters of pharmaceutical regulation. It enacted Act 358, which prohibits manufacturers from interfering with covered entities' ability to obtain and deliver discounted drugs through contract pharmacies. The statute does not seek to upend the federal scheme; rather, it seeks to preserve access to medicines for the populations Congress sought to protect.

States regulate pharmacies—and the distribution of drugs to those pharmacies—every day. Act 358 fits comfortably within that tradition. We hold that it is not preempted by federal law and does not violate the Takings

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[1] *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 115 (2011) (citations omitted).

Clause, the Contracts Clause, or the Due Process Clause's prohibition on vagueness. We further hold that the district court erred in permitting the Louisiana Primary Care Association to intervene, because it failed to show that it would offer any defense distinct from the State or that its divergent interests otherwise affect this litigation.

We therefore AFFIRM the district court's grant of summary judgment for Louisiana and REVERSE its order granting the LPCA's motion to intervene in the underlying *AbbVie* case.

I

A

Congress enacted 42 U.S.C. § 256b as part of the Veterans Healthcare Act of 1992.[2] Section 256b created what is commonly known as the 340B Program, which requires pharmaceutical manufacturers that participate in Medicaid and Medicare Part B to sell certain outpatient drugs at "no more than the statutorily-set ceiling price" to designated healthcare providers.[3]

These providers—called "covered entities"—include federally qualified health centers, family-planning projects, state-operated AIDS facilities, black lung clinics, and other safety-net institutions that serve low-income and uninsured patients.[4] In exchange for access to discounted drugs, the statute "places several key restrictions on covered entities," including

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[2] 42 U.S.C. § 256b.

[3] *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 639–40 (5th Cir. 2025) (per curiam) (citing 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1), (5) (internal quotation marks omitted)).

[4] *See* § 256b(a)(4) (defining covered entity).

prohibitions on duplicate discounts and drug diversion, audit requirements, and penalties for noncompliance.[5]

The Health Resources and Services Administration (HRSA), an agency within the Department of Health and Human Services, administers the 340B Program.[6] Manufacturers "opt into the 340B Program by signing" Pharmaceutical Pricing Agreements (PPAs) with HHS.[7] These agreements "are not transactional, bargained-for contracts"—rather, they are "uniform agreements" that merely "recite" the statutory obligations of manufacturers and the HHS Secretary.[8] By signing a PPA, a manufacturer agrees to provide 340B discounts to covered entities as a condition of receiving Medicaid and Medicare Part B reimbursements.

From the program's inception, Congress has said nothing about how discounted drugs must be dispensed. In 1996, HRSA issued guidance addressing that silence. Recognizing that many covered entities lacked in-house pharmacies—particularly in rural or underserved areas—HRSA permitted such entities to contract with a single outside pharmacy to dispense 340B drugs.[9] Under that arrangement, covered entities would purchase and pay for drugs, while manufacturers would ship them to the

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[5] *Fitch*, 152 F.4th at 640; §§ 256b(a)(5)(A)–(D).

[6] *See Astra*, 563 U.S. at 117 ("Congress vested authority to oversee compliance with the 340B Program in HHS.").

[7] *Id.* at 113.

[8] *Id.* at 113.

[9] *Notice Regarding Section 602 of the Veterans Health Care Act of 1992-Contract Pharmacy Services*, 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996).

"340B drugs" refer to the discounted drugs purchased by covered entities pursuant to 42 U.S.C. § 256b.

contract pharmacy for distribution to eligible patients. The pharmacy functioned solely as a distribution intermediary.

Fourteen years later, HRSA significantly expanded that model. In 2010, it issued guidance allowing *all* covered entities—including those with their own pharmacies—to contract with an unlimited number of outside pharmacies.[10] The effects were swift and significant. After the 2010 guidance, "the use of contract pharmacies skyrocketed."[11]

Manufacturers soon pushed back. Expressing concern that contract pharmacies were unlawfully profiting from these discounted drugs rather than merely dispensing them, manufacturers adopted policies limiting the distribution of Section 340B drugs through contract pharmacies.[12] In 2020, HHS responded, "act[ing] quickly" to issue an advisory opinion "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.'"[13] Unsurprisingly, manufacturers sued.

Both the Third Circuit and the D.C. Circuit rejected HHS's opinion, holding that the 340B statute does not require manufacturers to deliver

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[10] *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010).

[11] *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023).

[12] *Fitch*, 152 F.4th at 640–641.

[13] *Id.* at 641 (quoting *Advisory Op. 20-06 on Contract Pharmacies Under the 340B Program*, 2020 WL 11422965, at *1 (Dec. 30, 2020) (footnote omitted)).

discounted drugs to an unlimited number of contract pharmacies.[14] In the wake of those decisions, states began to "attempt to do by [state law] what HHS had done in its advisory opinion"[15]—thereby setting the stage for the dispute before us.

B

In 2023, Louisiana enacted Act 358, joining a growing number of states responding to manufacturers' restrictions on the distribution of 340B drugs.[16] The statute imposes two core prohibitions on manufacturers and distributors of 340B drugs:

> A. A manufacturer or distributor 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 and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.
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> B. A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.[17]

Violations of either provision constitute violations of Louisiana's Unfair Trade Practices and Consumer Protection Law,[18] exposing

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[14] *See Sanofi*, 58 F.4th at 703–04; *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 458 (D.C. Cir. 2024).

[15] *Fitch*, 152 F.4th at 641.

[16] *See, e.g.*, ARK. CODE ANN. § 23-92-604(c) (2021); MISS. CODE ANN. § 41-149-1 *et seq* (2024).

[17] LA. STAT. ANN. § 40:2884 (2023).

[18] *Id.* § 51:1401 *et seq*.

manufacturers to various "investigative demands, remedies, and penalties."[19]

C

Two manufacturers and one trade association promptly challenged Act 358 in separate suits against Louisiana's Attorney General, Liz Murrill, in her official capacity. Each asserted that Act 358 is preempted by § 340B—but each also advanced its own combination of federal constitutional claims seeking declaratory and injunctive relief.[20]

AbbVie, Inc. alleged federal preemption, an unconstitutional taking, and unconstitutional vagueness. AstraZeneca Pharmaceuticals, L.P. brought preemption and Contracts Clause claims. And Pharmaceutical Research & Manufacturers of America (PhRMA) asserted preemption and vagueness challenges.

The district court resolved all three cases together. In a single opinion, it denied the manufacturers' motions for summary judgment and granted summary judgment in favor of Louisiana—and the LPCA—on every claim.[21] The manufacturers appealed, and the three appeals are consolidated before us.

II

We review summary judgment *de novo*, "viewing all evidence in the light most favorable to the nonmoving party and drawing all reasonable

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[19] *Id.* § 40:2885.

[20] We note that the Louisiana Primary Care Association (LPCA) moved to intervene in each case, and only AbbVie opposed. The district court granted LPCA's intervention in each case.

[21] *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, Nos. 6:23-CV-997, 6:23-CV-1042, 6:23-CV-1307, 2024 WL 4361597, at *15 (W.D. La. Sept. 30, 2024).

inferences in that party's favor."[22] "Summary judgment is appropriate only when 'the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'"[23] "We may affirm a summary judgment on any ground supported by the record, even if it is different from that relied on by the district court."[24]

III

We begin, as always, with jurisdiction. Federal courts have subject-matter jurisdiction over cases "arising under" federal law.[25] And it is "well-established" that federal courts have jurisdiction over claims that assert federal preemption and seek declaratory and injunctive relief against a state official.[26]

Louisiana nonetheless argues that the district court lacked subject-matter jurisdiction over the manufacturers' preemption claims. In support, the State invokes our decision in *Elam v. Kansas City Southern*

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[22] *Sheet Pile, L.L.C. v. Plymouth Tube Co., USA*, 98 F.4th 161, 165 (5th Cir. 2024) (quoting *Pierce v. Dep't of U.S. Air Force*, 512 F.3d 184, 186 (5th Cir. 2007)).

[23] *Id.* (quoting FED. R. CIV. P. 56(a)).

[24] *Holtzclaw v. DSC Commc'ns Corp.*, 255 F.3d 254, 258 (5th Cir. 2001) (citing *Tex. Refrigeration Supply, Inc. v. FDIC*, 953 F.2d 975, 980 (5th Cir. 1992)).

[25] 28 U.S.C. § 1331.

[26] *Planned Parenthood of Hou. & Se. Tex. v. Sanchez*, 403 F.3d 324, 331 (5th Cir. 2005) (quoting *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96 n. 14 (1983) ("A plaintiff who seeks injunctive relief from state regulation, on the ground that such regulation is preempted by a federal statute which, by virtue of the Supremacy Clause of the Constitution, must prevail, thus presents a federal question which the federal courts have jurisdiction under 28 U.S.C. § 1331 to resolve.")); *see also New Orleans & Gulf Coast Ry. Co. v. Barrios*, 533 F.3d 321, 330 (5th Cir. 2008) ("[T]he principle articulated in *Shaw*—that a plaintiff who seeks injunctive relief on preemption grounds necessarily presents a federal question—does not apply in a suit exclusively between private parties, in the absence of some showing of state action.").

Railway Co., quoting the "black-letter" proposition that "[d]efensive preemption does not create federal jurisdiction and simply declares the primacy of federal law, regardless of the forum or the claim."[27]

That argument misses the mark. *Elam* involved a state-law tort action in which preemption was raised defensively.[28] This case is different. As AstraZeneca correctly observes, this is "a classic *Ex parte Young* suit."[29] The manufacturers invoke the Supremacy Clause as a sword, not a shield, seeking prospective relief against state officials alleged to be enforcing a preempted statute.

Defensive-preemption cases like *Elam*—which turn on the well-pleaded complaint rule, under which "a federal court does not have federal question jurisdiction unless a federal question appears on the face of the plaintiff's well-pleaded complaint"[30]—are therefore inapposite. Here, the federal question appears on the face of the complaint. Federal-question jurisdiction therefore exists.[31]

With jurisdiction secure, we turn to the merits. Each manufacturer presses a federal preemption challenge and advances additional constitutional claims. AbbVie contends that Act 358 violates the Takings Clause. AstraZeneca argues that the Act violates the Contracts Clause. And PhRMA asserts that the statute is unconstitutionally vague. We also address

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[27] 635 F.3d 796, 803 (5th Cir. 2011) (cleaned up).

[28] *See id.* at 802–04.

[29] *See Ex parte Young*, 209 U.S. 123 (1908); *see also Reed v. Goertz*, 598 U.S. 230, 234 (2023) ("[T]he *Ex parte Young* doctrine allows suits . . . for declaratory or injunctive relief against state officers in their official capacities.") (citing *Young*, 209 U.S. at 159–61)).

[30] *See Elam*, 635 F.3d at 803 (citation omitted).

[31] *See Planned Parenthood*, 403 F.3d at 331 (internal quotations omitted).

AbbVie's challenge to the district court's decision allowing LPCA to intervene. We consider each issue in turn.

IV

We begin with the claim common to all three manufacturers: federal preemption. The district court rejected AbbVie's, AstraZeneca's, and PhRMA's arguments that Act 358 is preempted by federal law under theories of field, conflict, or obstacle preemption. We agree.

A

The Supremacy Clause declares that "[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[32] Through it, Congress possesses "the power to preempt state law"[33]—either "through express language in a statute" or implicitly.[34] But the exercise of that power is not lightly presumed.

When evaluating preemption, we begin with the "presumption against preemption," particularly in "areas of law traditionally reserved to the states."[35] Public health and consumer protection fall squarely within a State's historic police powers. Where those interests are at stake, "the assumption [is] that the historic police powers of the States were not to be

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[32] U.S. CONST. art. VI, cl. 2.

[33] *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000); *see Gibbons v. Ogden*, 22 U.S. 1, 82 (1824).

[34] *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376 (2015).

[35] *Franks Inv. Co. LLC v. Union Pac. R.R. Co.*, 593 F.3d 404, 407 (5th Cir. 2010) (en banc) (cleaned up).

superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[36]

The manufacturers urge us to dispense with that presumption, arguing that Louisiana's police powers cannot regulate conduct touching the federal 340B Program. We are unpersuaded. Act 358 does not regulate the 340B Program itself. It regulates the distribution of drugs to patients and the role of pharmacies in this distribution—areas left free under the 340B Program for state supplementation.[37] In close cases, "when there is doubt about preemption, the tie goes to the state."[38]

We need not reinvent the wheel. Just months ago, we held in *AbbVie, Inc. v. Fitch* that Mississippi's materially indistinguishable law raises no preemption concerns—whether under field, conflict, or obstacle preemption.[39] *Fitch* controls here.[40]

Field preemption "fundamentally is a question of congressional intent."[41] It arises only when "Congress, acting within its proper authority, has determined [that certain conduct] must be regulated by its exclusive

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[36] *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

[37] *Fitch*, 152 F.4th at 646–47.

[38] *Id.*at 645 (internal quotation omitted).

[39] *Id.* at 645–48. The operative language of the Mississippi law is nearly identical to that of Act 358. *Compare* MISS. CODE ANN. § 41-149-7 (2024), *with* LA. STAT. ANN. § 40:2884 (2023).

[40] Plaintiffs attempt to cabin *Fitch*'s holding by emphasizing its language that the holding was based on the "specific claims and sparse record" of a preliminary-injunction proceeding. *See id.* at 639. Of course, we recognize the summary-judgment posture here. Even so, we are not only persuaded, but *bound*, by this on-point decision.

[41] *English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990).

governance," thereby leaving no room for state regulation.[42] For that reason, the Supreme Court has cautioned courts to hesitate to infer field preemption absent a showing of "complete ouster of state power."[43]

In *Fitch*, we examined § 340B—the very same federal program and statutory provision at issue here—and concluded that its regulatory scheme is not "so pervasive that Congress left no room for state supplementation."[44] We catalogued what § 340B *does* regulate: price ceilings for covered outpatient drugs; eligibility criteria for covered entities; prohibitions on duplicate discounts and diversion; audit and enforcement mechanisms; and the terms governing manufacturers' and wholesalers' sales of discounted drugs to covered entities.[45]

We also identified what § 340B conspicuously *does not* regulate: "neither the distribution of drugs to patients nor the role of pharmacies in this distribution"[46]—the precise subjects addressed by Mississippi's law in *Fitch* and Louisiana's Act 358 here. Our sister circuits have reached the same conclusion,[47] emphasizing § 340B's "silence" on contract pharmacies and delivery logistics.[48] Where Congress has left such matters "unaddressed in

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[42] *City of El Cenizo v. Texas*, 890 F.3d 164, 176 (5th Cir. 2018) (cleaned up).

[43] *De Canas v. Bica*, 421 U.S. 351, 357 (1976).

[44] *Fitch*, 152 F.4th at 646.

[45] *Id.*

[46] *Id.*

[47] *Id.*

[48] *See Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1144 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768 (2024) (noting "Congressional silence on pharmacies in the context of 340B"); *Sanofi*, 58 F.4th at 703 (describing Section 340B as "silent about delivery" of drugs to patients and contract pharmacies); *Novartis*, 102 F.4th at 460 (describing Section 340B as "silent about delivery conditions").

an otherwise comprehensive and detailed federal regulatory scheme," they "are presumably left subject to the disposition provided by state law."[49]

Further, as with Mississippi's analogous statute, Louisiana's Act 358 "implicates two traditional general areas of state regulation and police power: public health and consumer protection."[50] And because § 340B evinces "no clear and manifest intent to preempt state laws regulating the distribution of drugs to patients and the role of pharmacies in such distribution," Act 358 is not field preempted.[51]

Nor is it conflict preempted. "Conflict preemption applies (1) where complying with both federal law and state law is impossible; or (2) where the state law creates an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[52]

The manufacturers advance several conflict-preemption theories. None is persuasive.

First, AbbVie and PhRMA argue that Act 358 impermissibly "expands" the universe of covered entities by requiring manufacturers to provide discounted drugs to contract pharmacies. That argument ignores the basic mechanics of the 340B Program.

As we explained in *Fitch*, laws like Mississippi's—and Louisiana's—require manufacturers to provide discounted drugs to contract pharmacies "only insofar as they have partnered with covered entities to *distribute* the

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[49] *Fitch*, 152 F.4th at 646 (quoting *O'Melveny & Myers v. FDIC*, 512 U.S. 79, 85 (1994) (internal quotation marks omitted)).

[50] *Id.*

[51] *Id.* at 647.

[52] *Barrosse v. Huntington Ingalls, Inc.*, 70 F.4th 315, 320 (5th Cir. 2023) (quotation omitted), *cert. denied*, 144 S. Ct. 557 (2024).

drugs to patients."[53] Put simply: "[p]harmacies do not purchase 340B drugs, and they do not receive the 340B price discounts. Covered entities purchase and maintain title to the 340B-discounted drugs, while contract pharmacies dispense these drugs to covered entities' patients."[54] The manufacturers' contrary characterization was rejected in *Fitch* as "simply incorrect,"[55] and it fares no better here.

AbbVie and PhRMA's second conflict-preemption argument likewise falls short. They contend that Act 358 impermissibly "clashes with Congress's enforcement scheme" which vests HHS with exclusive authority to enforce 340B. That framing presents a false conflict. Two things can be true at once.

While "it is true that Congress made HHS the sole enforcer of Section 340B,"[56] it is also true that Louisiana's Attorney General enforces Act 358. The two regimes operate in distinct spheres. As Louisiana explains, if a manufacturer believes a covered entity has engaged in duplicate discounting, "only the 340B statute provides recourse . . . and Act 358 has nothing to say about it." Conversely, if a manufacturer refuses to deliver discounted drugs to a contract pharmacy acting on behalf of a covered entity, "only Act 358 provides recourse" because § 340B is silent on delivery

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[53] *Fitch*, 152 F.4th at 647 (emphasis added).

[54] *McClain*, 95 F.4th at 1144 (citing *Sanofi*, 58 F.4th at 700).

[55] *Fitch*, 152 F.4th at 647.

[56] *Id.*

logistics.[57] As in *Fitch*, there is no overlap in the enforcement Venn Diagram—and thus no conflict.[58]

We are similarly unpersuaded by AstraZeneca's obstacle-preemption theory. This argument rests on the premise that Act 358 "regulates pricing on its face." We reject that premise—just as the Eighth Circuit did when evaluating Arkansas's materially similar statute.[59]

AstraZeneca reasons that Act 358 must regulate pricing because a *violation* would occur whenever a manufacturer attempts to sell a § 340B drug at full price rather than the discounted price. But that is circular reasoning. Act 358 does not regulate prices; it regulates conduct. By its terms, the statute prohibits manufacturers from interfering with the "acquisition" by—

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[57] In its briefing and during oral argument, AbbVie emphasized § 340B's federal Alternative Dispute Resolution process, maintaining that Act 358 forces "Louisiana courts to answer the same questions as federal ADR panels." But AbbVie's own arguments highlight the flaw in its reasoning. It argues that Act 358 covers enforcement "whenever a manufacturer 'denies, restricts, or prohibits . . . acquisition of a 340B drug by, or delivery of a 340B drug'" to a contract pharmacy. *See* LA. STAT. ANN. § 40.2884(A). We note that AbbVie omitted the statutory prohibition on "interfere[nce]." *See id.* § 40:2884(B). Other than that, we agree with AbbVie's characterization. What we find surprising is AbbVie's concern that Act 358's enforcement scheme somehow conflicts with "the federal scheme [that] covers claims 'by a covered entity . . . that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price.'" *See* 42 C.F.R. § 10.21(a)(1). Act 358 provides the mechanism by which Louisiana can enforce the *delivery* of the 340B drugs to the contract pharmacies. By contrast, the federal scheme allows HHS to enforce covered entities' *ability to purchase* 340B drugs. These are distinct matters.

[58] *See Fitch*, 152 F.4th at 647–48 (finding no conflict with the Mississippi law's enforcement scheme because it "does not concern the same subject matter as Section 340B") (cleaned up).

[59] *See McClain*, 95 F.4th at 1142–45 (rejecting preemption arguments because the Arkansas law "does not require manufacturers to provide 340B pricing discounts to contract pharmacies" and "does not set or enforce discount pricing").

or "delivery" to—a "pharmacy that is under contract with a 340B entity."[60] The district court correctly recognized that distinction.[61]

AstraZeneca further argues that even if Act 358 does not regulate pricing, it nevertheless "'skews' the program's 'delicate balance of statutory objectives'" because Act 358 applies only to 340B participants. "As with any piece of legislation, Congress did indeed seek to strike a balance among a variety of interests" in enacting the Section 340B Program.[62] But "[p]art of that balance . . . involved allocating authority between the Federal Government and the States."[63] Congress decided not to undertake regulation of the delivery of 340B drugs or the role of pharmacies in that process—thereby leaving, absent congressional amendment, those matters to state law.

Act 358 operates comfortably within that space. The statute does not disturb the federally regulated relationship between manufacturers and covered entities. Manufacturers must still offer covered entities the 340B ceiling price, exactly as federal law requires. Act 358 comes into play only after a covered entity has purchased the drugs and directs their delivery to a contract pharmacy. Far from frustrating § 340B's objectives, the two laws work in tandem to advance Congress's central aim: ensuring that "manufacturers participating in Medicaid . . . offer discounted drugs to

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[60] LA. REV. STAT. § 40:2884(A).

[61] *See Murrill*, 2024 WL 4361597, at *8 (finding Act 358 "does not address the pharmaceutical companies' agreements with HHS or the pricing, diversion, or 'double dipping' restrictions addressed in the HHS[] enforcement scheme").

[62] *See Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 606–07 (2011) (plurality op.).

[63] *Id.*

covered entities, dominantly, local facilities that provide medical care for the poor."[64]

Federal law therefore does not preempt Act 358.

V

Because Act 358 is not preempted, we turn to the remaining constitutional claims—beginning with AbbVie's Takings Clause argument.[65]

"When the government physically acquires private property for a public use, the Takings Clause imposes a clear and categorical obligation to provide the owner with just compensation."[66] A physical taking occurs when the government "uses its power of eminent domain to formally condemn property" or when it "physically takes possession of property without acquiring title to it."[67] The government may also effect a taking—obligating the government to provide just compensation—through regulation. "[W]hen the government . . . imposes regulations that restrict an owner's ability to use his own property,"[68] courts must determine whether the restriction "goes too far,"[69] applying a fact-specific, "flexible test" that balances "the economic impact of the regulation, its interference with reasonable investment-backed expectations, and the character of the government action."[70]

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[64] *Astra*, 563 U.S. at 115.

[65] *See* U.S. CONST. amend. V.

[66] *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147 (2021).

[67] *Id.* (collecting cases).

[68] *Id.* at 148.

[69] *Id.* (quoting *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)).

[70] *Id.* (quoting *Penn Cent. Transp. Co. v. City of New York*, 348 U.S. 104, 124 (1978)).

AbbVie insists that Act 358 effects a *physical* taking, not a regulatory one. As a fallback, AbbVie argues that even if Act 358 is analyzed as a regulatory taking, it still violates the Fifth Amendment. Under either theory, AbbVie's claim fails.

We begin with AbbVie's frontline contention: that Act 358 effects a physical taking "because it compels the transfer of AbbVie's property to private parties that will sell the drugs at regular prices and retain the profit for themselves." That argument is foreclosed by *Fitch*.

In *Fitch*, AbbVie advanced the same theory against Mississippi's virtually identical statute. We rejected it, explaining that the law:

> [D]oes 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 [the Mississippi law], AbbVie still receives payment of the full discounted amounts to which it is entitled under Section 340B. [The Mississippi law] 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.[71]

The same is true here. Although AbbVie disagrees with *Fitch*'s characterization of how such statutes operate, it identifies no material difference between Mississippi's law and Act 358 that would justify a different result. We adhere to *Fitch*. Like its Mississippi counterpart, Act 358

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[71] *Fitch*, 154 F.4th at 643.

does not deprive AbbVie of anything to which § 340B entitles it. Act 358 does not compel manufacturers to "complete more sales in the first instance," as AbbVie asserts; rather, it applies only "*after* [covered entities] have purchased" the discounted drugs and directed their delivery.[72]

AbbVie's alternative regulatory-taking theory fares no better. In determining whether a law crosses the line between permissible regulation and impermissible taking, courts "balanc[e] factors such as the economic impact of the regulation, its interference with reasonable investment-backed expectations, and the character of the government action."[73] The first factor weighs against AbbVie. While Act 358 "could increase the number of drugs for which [AbbVie] must provide discounts . . . for most drugs, [AbbVie] will still receive a large percentage of the market price."[74] The second factor likewise cuts against AbbVie. Contract pharmacies have been part of the 340B landscape for decades, and Act 358 "does not significantly interfere" with AbbVie's reasonable investment-backed expectations.[75] Finally, the character of the government action favors the State. Act 358 advances a core public purpose: ensuring that low-income and rural patients have access to discounted medications.

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[72] *Id.* (emphasis added). We appreciate AbbVie's point that "[t]he 340B offer is *always* held open to *all* covered entities," so in practice, "there is no period" before the "offer" to a covered entity. But that does not lead to AbbVie's conclusion that Act 358 somehow forces a series of sales at the outset. It simply means Act 358 prevents drug makers from interfering *post*-sale.

[73] *Penn Cent.*, 348 U.S. at 124.

[74] *Fitch*, 152 F.4th at 644

[75] *Id.* (describing "the potential for dispensation of Section 340B drugs by contract pharmacies" as "foreseeable").

Relying on *Fitch*, we conclude that Act 358 effects neither a physical nor a regulatory taking.[76]

VI

We next consider AstraZeneca's Contracts Clause challenge.

The Contracts Clause limits a State's power to disrupt contractual relationships, providing that "[n]o State shall . . . pass any . . . Law impairing the Obligation of Contracts."[77] The Clause applies broadly—"to any kind of contract."[78] But it does not insulate contracts against all legislative change. As the Supreme Court has long recognized, "states have some leeway to alter parties' contractual relationships 'to safeguard the vital interests of [their] people.'"[79] Indeed, "parties contract with an expectation of possible regulation"—"especially . . . in highly regulated industries."[80]

To determine whether a law violates the Contracts Clause, the Supreme Court "has long applied a two-step test."[81] First, we ask whether the law "operate[s] as a substantial impairment of a contractual relationship."[82] This "threshold issue" considers factors such as "the extent

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[76] And following *Fitch*, because we reject both the physical and regulatory takings theories, "we need not consider the parties' additional arguments" regarding the voluntary participation doctrine, whether the alleged taking was for a "public use," or whether injunctive relief is available for a regulation that advances a public use. *Id.* at 644 n.4.

[77] U.S. CONST. art. I, § 10, cl. 1.

[78] *Sveen v. Melin*, 584 U.S. 811, 818 (2018) (citing *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 244–45 (1978)).

[79] *NextEra Energy Cap. Holdings, Inc. v. Lake*, 48 F.4th 306, 328 (5th Cir. 2022) (quoting *Energy Rsrvs. Grp., Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 410 (1983)).

[80] *Id.*

[81] *Sveen*, 584 U.S. at 819.

[82] *See id.* (quoting *Allied Structural Steel*, 438 U.S. at 244).

to which the law undermines the contractual bargain, interferes with a party's reasonable expectations, and prevents the party from safeguarding or reinstating [its] rights."[83] Only if a substantial impairment exists do we proceed to step two, examining the "means and ends" of Act 358—specifically whether it is "drawn in an 'appropriate' and 'reasonable' way to advance 'a significant and legitimate public purpose.'"[84]

Because Act 358 does not substantially impair AstraZeneca's contractual obligations, "we may stop after step one."[85]

AstraZeneca argues that Act 358 substantially impairs its contractual relationship with the federal government under its pharmaceutical pricing agreement (PPA). Under the § 340B Program, manufacturers sign PPAs with HHS promising to provide discounted drugs to covered entities as a condition of receiving Medicaid and Medicare Part B reimbursements. According to AstraZeneca, Act 358 interferes with that agreement by expanding the universe of covered entities and "imposing costly new obligations on it *only* as a result of entering into" the PPA.

We disagree. Act 358 does not alter the terms, rights, or obligations of AstraZeneca's PPA with the federal government. The statute regulates relationships between covered entities and their contract pharmacies—relationships to which AstraZeneca is not a party.[86] Where Act 358 addresses acquisition and delivery of discounted drugs to contract pharmacies, the PPAs are silent.

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[83] *Id.*

[84] *See id.* (quoting *Energy Rsrvs. Grp.*, 459 U.S. at 411–12).

[85] *See id.*

[86] *See* LA. STAT. ANN. § 40:2884 (2023).

Nor does Act 358 "undeniably expand[]" AstraZeneca's obligations to "provide discounts for unlimited contract pharmacy sales." The D.C. Circuit and Third Circuit decisions on which AstraZeneca relies held only that HHS lacks authority under § 340B to mandate delivery to unlimited contract pharmacies. They did not hold—nor suggest—that States lack authority to regulate delivery through their traditional police powers.[87]

AstraZeneca's reliance on *Allied Structural Steel Co. v. Spannaus* also fails. There, Minnesota imposed retroactive pension obligations that "substantially altered" contractual relationships by superimposing duties "conspicuously beyond those that it had voluntarily agreed to undertake."[88] The law imposed "a sudden, totally unanticipated, and substantial retroactive obligation," effectively rewriting the contract, and the Supreme Court held it unconstitutional.[89]

Act 358 does nothing of the sort. It does not rewrite PPAs or impose new contractual terms. AstraZeneca points to nothing in its PPA that addresses—much less limits—delivery to contract pharmacies.[90] And unlike Minnesota's statute in *Allied Structural Steel*, Louisiana's Act 358 implicates "traditional general areas of state regulation and police power,"[91] not "a field it had never before sought to regulate."[92]

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[87] *See Novartis*, 102 F.4th at 460, 464; *Sanofi*, 58 F.4th at 703.

[88] 438 U.S. at 240.

[89] *Id.* at 249.

[90] And, as the courts in *Novartis* and *Sanofi* concluded, the PPAs *couldn't* contain terms about contract pharmacies—because HHS lacked authority to regulate those entities. *See Novartis*, 102 F.4th at 460, 464; *Sanofi*, 58 F.4th at 703.

[91] *Fitch*, 152 F.4th at 646.

[92] *See Allied Structural Steel*, 438 U.S. at 249.

The absence of delivery terms in the PPAs is dispositive. Because delivery logistics were never part of the federal pricing agreements, a covered entity's decision to use a contract pharmacy—and Act 358's requirement that manufacturers not interfere with that choice—does not alter the contractual bargain between AstraZeneca and the federal government.

Reasonable expectations confirm the point. "Courts look to terms of the contract to determine the parties' reasonable expectations."[93] And where a "market [is] heavily regulated at the time the parties entered the contract," the parties are on notice that "the landscape [in which they do business] is subject to change."[94]

Consider *Energy Reserves Group, Incorporated v. Kansas Power and Light Company*.[95] There, the Supreme Court rejected a Contracts Clause challenge to a Kansas law imposing intrastate gas price controls—even though the contracts at issue contemplated only *federal* price regulation. The Court emphasized the natural gas industry's long history of pervasive regulation and held that the parties could not reasonably expect regulatory stasis. Although "Kansas did not regulate natural gas prices specifically," state authority to do so "was well established," and "its supervision of the industry was extensive and intrusive."[96] In that setting, the Court explained, parties could not claim that supplemental state regulation violated their contractual rights.[97]

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[93] *United Healthcare Ins. Co. v. Davis*, 602 F.3d 618, 628 (5th Cir. 2010) (citation omitted).

[94] *See id.* at 630–31 (citation omitted).

[95] 459 U.S. 400 (1983).

[96] *Id.* at 413–14.

[97] *Id.* at 416.

So too here. AstraZeneca entered into its PPA as part of a comprehensive federal program governing pharmaceutical pricing—within a heavily regulated industry in which state and federal oversight have long coexisted. "That history of regulation" puts manufacturers "on notice."[98] And while the PPAs do not expressly contemplate state regulation of delivery to contract pharmacies, that silence cuts against AstraZeneca, not in its favor. Because the agreements say nothing about delivery at all, AstraZeneca could not reasonably expect that delivery obligations would arise exclusively from federal law.

For all these reasons, Act 358 does not substantially impair AstraZeneca's contractual obligations under the PPA. The district court correctly concluded that Act 358 comports with the Contracts Clause.

VII

Nor is Act 358 unconstitutionally vague, as PhRMA contends.

"In our constitutional order, a vague law is no law at all."[99] The void-for-vagueness doctrine—a component of due process—"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.'"[100] But a law is unconstitutionally vague only when it fails to specify a standard of conduct "at all"—not when it merely "requires a person to conform his conduct to an imprecise but comprehensible normative standard."[101] In the civil context, the bar is

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[98] *See NextEra Energy*, 48 F.4th at 328.

[99] *United States v. Davis*, 588 U.S. 445, 447 (2019).

[100] *United States v. Lanier,* 520 U.S. 259, 266 (1997) (quoting *Connally v. Gen. Constr. Co.,* 269 U.S. 385, 391 (1926)).

[101] *Coates v. City of Cincinnati*, 402 U.S. 611, 614 (1971).

especially high: "[T]he statute must be so vague and indefinite as really to be no rule at all."[102]

Act 358 does not come close to that line. The statute provides that "[a] manufacturer . . . 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."[103] It further bars manufacturers from "interfer[ing] with a pharmacy contracted with a 340B entity."[104]

PhRMA's vagueness challenge focuses on a single word: "interfere." According to PhRMA, the term is so open-ended that it could "prohibit manufacturers from even asking for information" for audits, thus chilling lawful conduct.

The text forecloses that reading. Under the familiar canon *noscitur a sociis*, a word is "known by its associates."[105] "This canon 'counsels that a word is given more precise content by the neighboring words with which it is associated.'"[106] Here, "interfere" appears alongside "deny, restrict, prohibit"[107]—terms that plainly mean "to refuse to grant, to withhold"

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[102] *Tex. v. Democratic Party v. Abbott*, 961 F.3d 389, 409 (5th Cir. 2020) (quoting *Groome Res. Ltd. v. Par. of Jefferson*, 234 F.3d 192, 217 (5th Cir. 2000)).

[103] La. Stat. Ann. § 40:2884(A) (2023).

[104] *Id.* § 40:2884(B).

[105] Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 195 (2012); *see also Yates v. United States*, 574 U.S. 528, 543 (2015).

[106] *Easom v. US Well Servs., Inc.*, 37 F.4th 238, 243 (5th Cir. 2022) (quoting *United States v. Williams*, 553 U.S. 285, 294 (2008)).

[107] *See* § 40:2884(A).

(deny),[108] "to limit, to confine" (restrict),[109] and "to forbid by authority or command, to interdict" (prohibit).[110] Read in context, "interfere" targets conduct that obstructs or impedes the acquisition or delivery of 340B drugs to contract pharmacies—not routine communications or lawful auditing practices. While that standard may be "imprecise" at the margins, it is readily "comprehensible."[111] Act 358, therefore, is not unconstitutionally vague.

VIII

Finally, we address LPCA's intervention, which we review *de novo*.[112]

In each of the three consolidated cases, LPCA moved to intervene—though we address it only in AbbVie's case because the other Plaintiffs do not challenge the intervention. We recognize our "broad policy favoring intervention"[113] and the principle that "[f]ederal courts should allow intervention where no one would be hurt and the greater justice could be

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[108] *Deny*, WEBSTER'S NEW INT'L DICTIONARY (2d ed. 1939).

[109] *Restrict*, WEBSTER'S NEW INT'L DICTIONARY (2d ed. 1939).

[110] *Prohibit*, WEBSTER'S NEW INT'L DICTIONARY (2d ed. 1939).

[111] *See Coates*, 402 U.S. at 614. We note that the use of "interfer[e]" in § 40:2884(B) likewise clears the void-for-vagueness bar—even though that provision does not mention the neighboring words of "deny, restrict, prohibit." *See* § 40:2884(B). Our precedent requires a statute to provide "a fair and reasonable warning," not "the utmost precision." *Echo Powerline, L.L.C. v. Occupational Safety & Health Rev. Comm'n*, 968 F.3d 471, 477 (5th Cir. 2020). Section 40:2884(B)'s prohibition on "interfer[ing] with a pharmacy contracted with a 340B entity" does just that.

[112] *Sierra Club v. Espy*, 18 F.3d 1202, 1205 (5th Cir. 1994).

[113] *Wal-Mart Stores, Inc. v. Texas Alcoholic Beverage Comm'n*, 834 F.3d 562, 569 (5th Cir. 2016).

attained."[114] Even so, although "Rule 24 is to liberally construed,"[115] the movant still "bears the burden of establishing its right to intervene."[116] LPCA has not met that burden here.

To intervene as of right under Rule 24(a)(2),[117] LPCA must satisfy four requirements:

> (1) the application for intervention must be timely; (2) the applicant must have an interest relating to the property or transaction which is the subject of the action; (3) the applicant must be so situated that the disposition of the action may, as a practical matter, impair or impede his ability to protect that interest; (4) the applicant's interest must be inadequately represented by the existing parties to the suit.[118]

Here, the fourth prong is dispositive. When a State is already a party, "the applicant for intervention must demonstrate that its interest is in fact different from that of the state and that the interest will not be represented by the state."[119] But an applicant need not show that representation by the State will certainly be inadequate; rather, an applicant satisfies this requirement when it shows that representation of its interests "may be" inadequate.[120] That requirement flows from the settled presumption that,

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[114] *Sierra Club*, 18 F.3d at 1205 (internal quotation marks and citation omitted).

[115] *Brumfield v. Dodd,* 749 F.3d 339, 341 (5th Cir. 2014) (citation omitted).

[116] *Id.*

[117] FED. R. CIV. P. 24(a)(2).

[118] *Texas v. United States*, 805 F.3d 653, 657 (5th Cir. 2015) (internal quotation marks and citation omitted).

[119] *Hopwood v. Texas*, 21 F.3d 603, 605 (5th Cir. 1994) (citations omitted).

[120] *Texas*, 805 F.3d at 661 (citation omitted).

"[i]n a suit involving a matter of sovereign interest, the State is presumed to represent the interests of all of its citizens."[121]

Only AbbVie opposes LPCA's intervention. It argues that "LPCA's interests are adequately represented by the Attorney General" of Louisiana and that, because LPCA lacks any right to enforce Act 358, it "has no interest" requiring protection. LPCA responds that it is intervening as a defendant, not suing, and that its interests diverge from the State's because Louisiana "has a broad interest in protecting laws that impact the public health of Louisianans," whereas LPCA seeks to protect the business interests of its members. LPCA does not explain why or how its divergent interests would affect the defense of this case.

We rejected similar reasoning in *Hopwood v. Texas*.[122] There, private organizations sought to intervene alongside Texas to defend the State's affirmative-action policy, asserting that their interests were more focused and that the State's broader obligations would dilute its defense. They contended that "the State must balance competing goals," whereas they were "sharply focused on preserving the admissions policy," and that the State therefore was "not in as good a position to bring in evidence" supporting the policy.[123] We disagreed, holding that the proposed intervenors failed to show either that they possessed an interest "that the State w[ould] not adequately represent" or that the State would not "strongly defend its affirmative action

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[121] *Hopwood*, 21 F.3d at 605.

[122] 21 F.3d 603, 605 (5th Cir. 1994) (internal citation omitted). LPCA is correct that we have held that "associations representing licensed business owners have a right to intervene in lawsuits challenging the regulatory scheme that governs the profession." *Wal-Mart Stores*, 834 F.3d at 567.

[123] *Hopwood*, 21 F.3d at 605.

program."[124] Critically, they also failed to demonstrate that they may offer any defense distinct from the one the State intended to present.[125]

The same is true here. LPCA has not shown that it would advance a defense of Act 358 different from Louisiana's. At most, it has shown that it would be an *additional* defender—not a *necessary* one. Under our precedent, that is insufficient where the State is already a party presumed to represent the relevant interests.

Because LPCA failed to satisfy Rule 24(a)(2)'s inadequate-representation requirement, its intervention was improper.

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Accordingly, we AFFIRM summary judgment for Louisiana on all counts and REVERSE the district court's order permitting LPCA to intervene in *AbbVie*'s case.

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[124] *Id.* at 606 (cleaned up).

[125] *Id.* (citation omitted).