United States Court of Appeals for the Fifth Circuit

No. 23-20533

United States Court of Appeals
Fifth Circuit
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Lyle W. Cayce
Clerk

ZYLA LIFE SCIENCES, L.L.C.,

Plaintiff—Appellant/Cross-Appellee,

versus

WELLS PHARMA OF HOUSTON, L.L.C.,

Defendant—Appellee/Cross-Appellant.

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 4:22-CV-4400

Before HO, DUNCAN, and OLDHAM, *Circuit Judges*.

ANDREW S. OLDHAM, *Circuit Judge*:

The question presented is whether a State triggers implied obstacles-and-purposes preemption when it expressly incorporates federal law into state law. The district court held yes. But as the Supreme Court held almost a century ago, "there is no conflict in terms, and no possibility of such conflict, for the state statute makes federal law its own." *California v. Zook*, 336 U.S. 725, 735 (1949). Therefore, we reverse.

I

A

1

All preemption has a constitutional source: the Supremacy Clause. *See Philadelphia v. New Jersey*, 430 U.S. 141, 142 (1977) (per curiam). In "our federal system, the States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause." *Tafflin v. Levitt*, 493 U.S. 455, 458 (1990). Under the Supremacy Clause, any state law that contradicts federal law is preempted. *See* U.S. CONST. art. VI, cl. 2. But barring any contradiction, the States retain their sovereign prerogatives to regulate.

Supreme Court precedent establishes a preemption taxonomy. The first division is between express and implied preemption. *Kansas v. Garcia*, 589 U.S. 191, 202–03 (2020). Implied preemption is further divided into two types: field preemption and conflict preemption. *Id.* at 208–211. Conflict preemption is then divided into two more types. The first is impossibility preemption. It arises when it is impossible to obey both state and federal requirements. *See Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963). The second is obstacles-and-purposes preemption (the only type of preemption at issue here). It arises when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). In all these types of preemption, however, "[e]vidence of pre-emptive purpose [must be] sought in the text and structure of the [federal provision] at issue." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

The federal provisions at issue here come from the Federal Food, Drug, and Cosmetic Act ("FDCA"). On June 25, 1938, President Franklin Delano Roosevelt signed the FDCA into law. *See* Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 301 *et seq.*). The New Dealers who drafted the FDCA did not start from scratch, though. They responded to perceived weaknesses in the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938), which was signed by Roosevelt's fifth cousin by blood and uncle by law, President Theodore Roosevelt.

The weaknesses with the 1906 Act were brought into the American consciousness by Arthur Kallet and F.J. Schlink's 1933 bestseller, *100,000,000 Guinea Pigs: Dangers in Everyday Foods, Drugs, and Cosmetics*. *See* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 5–6 (1939). Kallet and Schlink warned that the American people had been "forced into the role of laboratory guinea pigs" by "the food and drug industries," which had "been making profits by experimenting on [Americans] with poisons, irritants, harmful chemical preservatives, and dangerous drugs." ARTHUR KALLET & F.J. SCHLINK, 100,000,000 GUINEA PIGS: DANGERS IN EVERYDAY FOODS, DRUGS, AND COSMETICS 4 (1933). Kallet and Schlink told the stories of men like "William J. A. Bailey, an ex-auto-swindler," who made his "money by dissolving radium salts in water and selling" the resultant concoction "to rich men to cure their ills." *Id.* at 4–5. To the horror of Kallet and Schlink's readers, "Bailey's radium water" had "sent at least two men to horrible deaths." *Id.* at 5. More horrifying still was Kallet and Schlink's premonition that "a similar fate may be awaiting scores or hundreds of others who drank this deadly fluid." *Ibid.*

The centerpiece of the new FDCA was § 505. *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1761 (1996). Although that provision "was not among the reforms originally sought by the [FDCA's] architects," *ibid.*, it became the focal point of the new FDCA after nearly a hundred Americans died of poisoning from the "Elixir Sulfanilamide" drug sold by the S. E. Massengill Company, *see* Cavers, *supra*, at 20. In response to this tragedy, Congress determined that the Federal Government should act to prevent such incidents from occurring in the first place, rather than merely "respond[] to evidence of harm" after it had occurred. Merrill, *supra*, at 1761. So Congress decided to forbid manufacturers from marketing drugs "without first notifying [the] FDA and allowing it time to assess their safety." *Id.* at 1762. After further amendments in 1962, Congress converted this "premarket *notification* system" into today's "premarket *approval* system." *Id.* at 1764–65 (emphasis added). Under today's system, no one may sell "any new drug" without prior approval from the FDA. *See* 21 U.S.C. § 355(a).

Ever since the FDCA's enactment in 1938, Congress has given the Federal Government power to enforce its substantive provisions. *See* 52 Stat. at 1046. Today, those enforcement provisions are codified at 21 U.S.C. § 337. Subsection (a) authorizes the United States to bring "all . . . proceedings for the enforcement, or to restrain violations," of the FDCA. And subsection (b) permits States to bring actions to enforce certain provisions of the FDCA.

Originally, the FDCA did not regulate all aspects of drug safety: As relevant here, it left alone the ancient art of compounding. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362 (2002); *see also* JUDITH E. THOMPSON, A PRACTICAL GUIDE TO CONTEMPORARY PHARMACY PRACTICE 141 (3d ed. 2009) (discussing compounding's ancient roots). Compounding fell outside the FDCA's premarket approval scheme for new

drugs. Compounders, after all, do not make *new* drugs; they merely "combine[], mix[], and alter[]" the "ingredients in" old drugs. *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs.*, 48 F.4th 1040, 1042 (9th Cir. 2022). The goal of compounding is to provide "medication tailored to the needs of an individual patient." *Thompson*, 535 U.S. at 360–61. For example, some infants and children might need a certain medication, but the commercially available forms of the medication provide too high a dosage. THOMPSON, *supra*, at 142. Other patients might be allergic to some ingredient in the commercially available forms. *Ibid.* That's where compounding comes in. Under the original FDCA, and for roughly a half-century thereafter, compounding regulation was "generally left . . . to the States." *Thompson*, 535 U.S. at 362.

Eventually, though, the Federal Government grew "concerned . . . that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Ibid.* Even as the Federal Government began to regulate compounding, Congress maintained a limited exemption from the FDCA's premarket-approval requirement for certain drugs "compounded for an identified individual patient." Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, 2328 (codified as amended at 21 U.S.C. § 353a). And as relevant in this case, in 2013, Congress also crafted an exemption for certain registered compounding facilities. *See* Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587, 588 (2013) (codified at 21 U.S.C. § 353b). But under § 353b, registration alone is not enough for a facility to sell compounded drugs without premarket approval. The compounding facility must satisfy a host of additional statutory criteria. *See ibid.*

3

In the face of this ever-expanding federal regulation of drugs, however, the States have not forfeited their traditional prerogative to police drug

safety. *Cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (highlighting "the historic primacy of state regulation of matters of health and safety"). As relevant here, six States have decided to mirror federal law by making it illegal to sell any new drug that has not been approved under 21 U.S.C. § 355 (the original § 505 of the FDCA). *See* CAL. HEALTH & SAFETY CODE § 111550(a); COLO. REV. STAT. § 12-280-131(1); CONN. GEN. STAT. § 21a-110; FLA. STAT. § 499.023; TENN. CODE § 53-1-110(a); S.C. CODE § 39-23-70(a). If anyone sells drugs in violation of these state laws, competitors may bring suit under traditional state unfair-competition law.

B

This dispute arises between two such competitors: Zyla Life Sciences, LLC ("Zyla") and Wells Pharma of Houston, LLC ("Wells Pharma").

Zyla sells Indocin Suppositories across the United States.[1] Zyla's suppositories contain indomethacin, a drug used to treat various ailments, such as rheumatoid arthritis. At least until 2023, Zyla's suppositories were the only ones containing indomethacin that had obtained FDA approval.

Wells Pharma sells compounded indomethacin suppositories. Although the compounded indomethacin suppositories Wells Pharma sells are not FDA-approved, Wells Pharma satisfies at least one of § 353b's many requirements since it is a registered compounding facility under that section.

Zyla wanted to enjoin Wells Pharma from manufacturing and selling its suppositories in California, Colorado, Connecticut, Florida, South Carolina, and Tennessee, so it filed suit under those States' unfair-competition laws. Wells Pharma filed a motion to dismiss under Rule 12(b)(6), arguing

[1] Suppositories like Zyla's deliver medication into the body via small, round or cone-shaped objects. People place suppositories into their body—ordinarily in less-than-pleasant places—and once inside, the suppositories dissolve, releasing the medication.

the state laws were preempted. The district court granted the motion. Zyla appealed.

The question presented on appeal is whether the state laws somehow conflict with the FDCA by incorporating it.[2]

II

They do not. As we explain, (A) under *Zook*, Wells Pharma's conflict-preemption defense must fail. And (B) Wells Pharma's arguments to the contrary are unpersuasive.

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[2] We address three other theories of preemption briefly in this footnote.

First, field preemption is foreclosed by *Wyeth v. Levine*, 555 U.S. 555 (2009). *See id.* at 575.

Second, impossibility preemption is irrelevant. It is obviously possible to comply with identical requirements.

The third potential theory, which the district court embraced below, is a bit more complex. The district court concluded that the state laws were preempted because they added to federal requirements. *Zyla Life Scis., LLC v. Wells Pharma of Hous., LLC*, No. 4:22-CV-04400, 2023 WL 6301651, at *4–5 (S.D. Tex. Sept. 27, 2023). The district court reasoned that the state laws required Wells Pharma to obtain prior approval from the FDA. *Ibid.* But under federal law, Wells Pharma did not need to obtain approval if it satisfied § 353b. *Ibid.*

That's a big if. Because there is no preemption overbreadth doctrine, to establish its preemption defense, Wells Pharma needed to prove that the state laws were preempted "as applied" to it. *Kansas v. Garcia*, 589 U.S. 191, 208, 211 (2020); *see also Moody v. NetChoice, LLC*, 144 S. Ct. 2383, 2397 (2024). So to establish this theory of preemption, Wells Pharma needed to prove that the state laws impose additional requirements *as to Wells Pharma*. But the state laws do that only if Wells Pharma satisfies the many requirements of § 353b. Otherwise, the state and federal requirements are the same: To sell drugs, Wells Pharma must obtain FDA approval. But at this stage of the litigation, Wells Pharma cannot have proven that it satisfies § 353b's many requirements. Wells Pharma has only moved to dismiss under 12(b)(6). And given this procedural posture, we cannot draw factual inferences in Wells Pharma's favor concerning its compliance with § 353b.

A

Zook controls this case. *Zook* involved a California law that "prohibit[ed] the sale or arrangement of any transportation over public highways of the State if the transporting carrier ha[d] no permit from the Interstate Commerce Commission." 336 U.S. at 726. A federal statute had an identical provision. *Id.* at 726–27. After Berl B. Zook and Wilmer K. Craig violated the state law, California prosecuted them. *Id.* at 727. Zook and Craig argued that the California law was preempted because it mirrored federal law. *See id.* at 732–33.

The Supreme Court held that the California law was not preempted. The mere "fact of identity," the Court explained, did "not mean the automatic invalidity of State measures." *Id.* at 730. On the contrary, there was "no conflict in terms, and no possibility of such conflict, for the state statute ma[de] federal law its own." *Id.* at 735; *see also Garcia*, 589 U.S. at 212 ("[T]here is no basis for inferring that federal . . . statutes preempt state laws whenever they overlap."). Since there was no conflict, the state statute was not preempted.

Zook accords well with preemption first principles. As explained, preemption doctrine comes from the Supremacy Clause. But as the Supreme Court explained over a century ago, when state law mirrors federal law, it "recognizes the supremacy of the national law" by "conform[ing] to it." *Asbell v. Kansas*, 209 U.S. 251, 258 (1908).

Because the States' laws "recognize[] the supremacy of the national law," *ibid.*, it would be anomalous to conclude the Supremacy Clause somehow preempts them. Take the California statute underlying one of Zyla's claims, for example. It bars selling a "new drug" that has not been approved "under Section 505 of the [FDCA]." CAL. HEALTH & SAFETY CODE

§ 111550(a). The other state laws are identical in all relevant respects.[3] Those statutes all "make[] federal law [their] own." *Zook*, 336 U.S. at 735. Thus, there can be "no conflict in terms" and no preemption. *Ibid.*

B

Adopting Wells Pharma's contrary position would raise a host of legal problems. It would (1) mark the return of an *ancien régime* of preemption rejected both by Congress and the Supreme Court. (2) The logic of Wells Pharma's position would undermine state sovereignty. Fortunately, (3) that logic has been repudiated in multiple throughlines of preemption and federalism precedent.

1

Adopting Wells Pharma's position would mark a return to the *ancien régime* of *Houston v. Moore*, 18 U.S. (5 Wheat.) 1 (1820). In *Houston*, Pennsylvania sought to punish a militiaman for refusing to respond when called into federal service "in pursuance of a requisition from the President of the United States" during the War of 1812. *Id.* at 3. The Pennsylvania law provided that any militiaman who "neglected or refused to serve when called

[3] *See* FLA. STAT. § 499.023 ("A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the [FDCA]. . . ."); TENN. CODE § 53-1-110(a) ("No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the [FDCA]."); S.C. CODE § 39-23-70(a) ("No person shall introduce or deliver for introduction into intrastate commerce any new drug unless . . . an application with respect thereto has been approved and such approval has not been withdrawn under Section 505 of the [FDCA]."); CONN. GEN. STAT. § 21a-110(a) ("No person shall sell . . . any new drug" that has not "been approved under Section 355 [§ 505 of the FDCA]."); COLO. REV. STAT. § 12-280-131(1) ("No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law.").

into actual service, in pursuance of any order or requisition of the President of the United States," would "be liable to the penalties" set out in various "act[s] of the Congress of the United States." *Id.* at 2. In other words, the Pennsylvania law punished the failure to report precisely to the extent federal law did.

Justice Bushrod Washington concluded that the Pennsylvania law was preempted. Washington proclaimed that he could not even fathom how two parallel laws could *not* contradict: As he put it, "I am altogether incapable of comprehending how two distinct wills can, at the same time, be exercised in relation to the same subject, to be effectual, and at the same time compatible with each other." *Id.* at 23. Since the Pennsylvania law sought to act upon "the same subject" as the federal law, it could not be "compatible with" federal law. *Ibid.* Since it was not compatible with federal law, it was preempted.

But "the *Houston* rule was doomed" from the start. J.A.C. Grant, *The Scope and Nature of Concurrent Power*, 34 COLUM. L. REV. 995, 1012 (1934).

First, Washington's opinion "cannot be said to have spoken for the Court." DAVID P. CURRIE, THE CONSTITUTION IN THE SUPREME COURT: THE FIRST HUNDRED YEARS, 1789–1888, at 110 (1992). Although a majority agreed with Washington that the judgment should stand, Washington himself acknowledged that the other justices who formed the majority did "not concur in all respects in the reasons which influence[d] [his] opinion." *Houston*, 18 U.S. (5 Wheat.) at 32. Thus, as Justice Johnson explained in his concurrence, "there [was] no point whatever decided." *Id.* at 47 (Johnson, J., concurring). So Washington's opinion was not precedential.

Second, "the premise upon which" Washington "based" his opinion was "unsound." Grant, *supra*, at 1012. Washington's "assumption that two distinct wills [could] not, in the nature of things, be exercised in relation to

the same subject at the same time" was "arid logic." *Ibid.* Washington himself thought that when two laws "correspond in every respect," as is the case when state law mirrors federal law, the state provision is only "idle and inoperative." *Houston*, 18 U.S. (5 Wheat.) at 23. A conflict occurs, thought Washington, only when the laws "differ." *Ibid.* But since an "idle" law is not a conflicting law, there is no reason to think it should be preempted even under Washington's own theory of preemption.

Regardless, a parallel state law would not be "idle." States may have a legitimate interest in punishing or providing redress for wrongs even if federal law already does so. The Federal Government is not the only one with an interest in criminalizing murder or rape. *See Zook*, 336 U.S. at 738 ("[T]he State may punish . . . for the safety and welfare of its inhabitants; the nation may punish for the safety and welfare of interstate commerce. There is no conflict."). Nor is it the only government with an interest in providing remedies for civil wrongs. *Cf. Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 249 (1984). Indeed, the Federal Government often has an interest in allowing parallel state regulation. For that reason, "the Federal Government fully supports [Zyla's] position," *Garcia*, 589 U.S. at 212, as it has shown by filing an amicus brief in a related case not long ago. *See* Brief for the United States as Amicus Curiae, *Athena Cosmetics, Inc. v. Allergan, Inc.*, 576 U.S. 1054 (2015) (No. 13-1379), 2015 WL 2457643. That should surprise no one. The Federal Government has limited resources. Thus, it often welcomes state aid in enforcing shared legal norms.

And Washington's opinion has been thoroughly repudiated. Just a few years after *Houston*, Congress rejected its understanding of congressional intent. Congress passed a statute explaining that federal criminal legislation should not "be construed to deprive the courts of the individual state of jurisdiction," under their *own* parallel laws, "over offenses" that federal law also criminalized. *See* Crimes Act of 1825, ch. 65, § 26, 4 Stat. 115, 122–23;

see also United States v. Coombs, 37 U.S. 72, 81 (1838).[4] And of course, *Zook* also rejected Washington's opinion. *See supra*, Part II.A (describing *Zook*); *see also Garcia*, 589 U.S. at 212.

2

The logic of Wells Pharma's position would undermine state sovereignty and principles of federalism. Start with Wells Pharma's theory. It contends the conflict comes from the FDCA's allocation of enforcement discretion to the Federal Government. In short, allowing States to enforce their own parallel laws would upset the discretion given to federal officials in enforcing the FDCA.

Now consider some of the state criminal laws Wells Pharma's theory would require us to find preempted. Federal law allocates exclusive enforcement discretion to the Federal Government over "offenses against the United States." *See* 28 U.S.C. § 547 (imposing enforcement duties upon the U.S. attorneys); 28 U.S.C. § 519 (granting the Attorney General authority to "supervise all" such "litigation"). And "[t]he district courts of the United

[4] True, *Houston* and the congressional response to it dealt only with parallel criminal laws. But if parallel criminal laws are not preempted, it follows *a fortiori* that parallel civil laws are not. Parallel criminal laws raise the concern that "enforcement officers are able to circumvent the constitutional guarantees against a second jeopardy for the same offense." Grant, *supra*, at 996–97; *see also* U.S. CONST. amend. V (forbidding anyone from being "twice put in jeopardy of life or limb" "for the same offence"); *Gamble v. United States*, 587 U.S. 678, 681 (2019) (recognizing the dual-sovereignty doctrine which permits "a State [to] prosecute a defendant under state law even if the Federal Government has prosecuted him for the same conduct under a federal statute"). Because of these background constitutional norms, the arguments for interpreting federal law to preempt parallel criminal laws are much more forceful than they are for parallel civil laws, as Justice Bushrod Washington's opinion in *Houston* recognized. *See* 18 U.S. (5 Wheat.) at 23 (explaining that parallel laws were "particularly" concerning "in a case inflicting pains and penalties"). Constitutional concerns sounding in double jeopardy, of course, do not arise in the context of parallel civil laws.

States" have "exclusive" jurisdiction over such "offenses." 18 U.S.C. § 3231. Still, many state statutes incorporate federal criminal requirements. Such statutes touch on areas ranging from the most mundane,[5] to the constitutionally controversial,[6] to the classic criminal.[7] All those laws, under Wells Pharma's theory, would be preempted because they purportedly undermine U.S. Attorneys' enforcement discretion.

Adopting Wells Pharma's theory would also undermine traditional state tort laws. For instance, violation of a federal statute often constitutes a breach of the duty of care under the negligence *per se* doctrine. *See* Restatement (Third) of Torts § 14 (2010); *see also Wiersgalla v. Garrett*, 486 N.W.2d 290, 292–93 (Iowa 1992) (acknowledging that violation of a federal statute or regulation may constitute negligence *per se*); Barbara Kritchevsky, *Tort Law Is State Law: Why Courts Should Distinguish State and Federal Law in Negligence-Per-Se Litigation*, 60 AM. U. L. REV. 71, 91 (2010) (explaining that "[m]ost courts . . . find no distinction between state and federal law in applying the doctrine of negligence per se"). Under Wells Pharma's theory, that would be preempted in any case in which the federal statute at issue vests

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[5] *See, e.g.*, NEV. REV. STAT. § 193.340 ("A provider of Internet service who violates the provisions of 18 U.S.C. § 2703 is guilty of a misdemeanor"); KY. REV. STAT. § 222.429 (barring "solicit[ing] or receiv[ing] any remuneration . . . for referring a resident to a treatment program" unless such conduct is permitted under 18 U.S.C. § 220 and conversely barring any conduct which violates 18 U.S.C. § 220(b)).

[6] *See, e.g.*, N.M. STAT. § 30-7-7.1 (providing that a person generally cannot sell firearms "without conducting a federal instant background check" unless they "hold[] a current and valid federal firearms license" under 18 U.S.C. § 923(a)); TENN. CODE § 39-17-1316(a)(1)(A)(iii) (barring selling firearms to anyone "ineligible to receive firearms under 18 U.S.C. § 922").

[7] *See, e.g.*, CONN. GEN. STAT. §§ 21a-243(g)–(h), 279 (generally incorporating the Federal Controlled Substances Act); MICH. COMP. LAWS §§ 333.7204, 7403 (similar).

enforcement discretion in the federal government with limited state or private involvement.

Moreover, if the concern is that state law will interfere with federal enforcement discretion, it is not only parallel laws that should be preempted; any state laws that regulate the same primary conduct as federal law should also be preempted. If anything, parallel standards, which ensure that the same primary conduct is regulated *in the same way*, pose reduced risk to federal enforcement priorities as compared to non-parallel standards, which regulate the same primary conduct *in different ways*. So under Wells Pharma's theory, any time a State regulates the same conduct that the Federal Government does, the state regulation should be preempted because it might upset federal enforcement prerogatives.

The implications are staggering. Given the extraordinary reach of federal law in our post-*Wickard* world, the Federal Government has its hands in nearly every facet of human existence. *See Wickard v. Filburn*, 317 U.S. 111 (1942); *see also Escobedo v. Ace Gathering, Inc.*, No. 23-20494, 2024 WL 5443121, at *2 (5th Cir. Sept. 30, 2024) (Oldham, J., dissenting from denial of rehearing en banc). Under our circuit's precedent, for instance, the Federal Government may regulate "subterranean, eyeless arachnids, ranging in size from 1.4mm to 4mm, that are born, reproduce, and die without ever leaving a cave in Texas and have zero connection to economic activity of any kind." *Escobedo*, 2024 WL 5443121, at *2. So if Wells Pharma's theory is correct, the States would be deprived of just about any power to regulate any conduct at all, simply because of a judicial hunch concerning mysterious congressional purposes allegedly lurking in the bowels of the U.S. Code. Practically any conduct the State wants to regulate is already regulated by the Federal Government. So state regulation would be preempted. But as the Founders understood, one of the fundamental features of sovereignty is the power to regulate "every thing that passes" within one's own territory.

EMER DE VATTEL, THE LAW OF NATIONS, § 204 (1797). So by preventing the States from regulating just about anything federal law touches, we judges would bring to fruition the Anti-Federalists' worst fear: the "entire subversion . . . of the individual states" to an all-powerful federal overlord. Brutus XI, ¶ 2.9.139, *in* 2 THE COMPLETE ANTI-FEDERALIST 420 (Herbert Storing ed., 1981) ("STORING"); *see also* Centinel II ¶ 2.7.17, *in* 2 STORING 141.

3

Fortunately for our federal system, Wells Pharma's logic has been rejected in at least four ways.

First, States may generally regulate the same conduct the Federal Government does. *See* RICHARD H. FALLON ET AL., HART AND WECHSLER'S FEDERAL COURTS AND THE FEDERAL SYSTEM 680 (7th ed. 2015); *see also Gamble v. United States*, 587 U.S. 678, 690 (2019). That is especially so when state standards mimic federal ones, as in this case. *See Zook*, 336 U.S. at 735.

Second, the "possibility that federal enforcement priorities might be upset is not enough to provide a basis for preemption." *Garcia*, 589 U.S. at 212.

Third, it is irrelevant that the States have provided remedies under state law that supplement the FDCA's remedial scheme. Providing redress for a civil wrong under state law does not create a conflict with a distinct "federal remedial scheme." *Silkwood*, 464 U.S. at 257. State law often provides remedies federal law does not. *See California v. ARC Am. Corp.*, 490 U.S. 93 (1989) (permitting States to offer remedies to certain individuals under state antitrust laws despite federal antitrust law not providing any remedy to those same individuals).

Fourth, under *Wyeth v. Levine*, 555 U.S. 555 (2009), the FDCA itself permits States to regulate conduct related to drug safety and effectiveness concurrently with the Federal Government. In *Wyeth*, a Vermont court held a drug manufacturer liable under state tort law for failure to provide an adequate warning on its label for the drug Phenergan. *Id.* at 558. But "[t]he warnings on Phenergan's label had been deemed sufficient by the [FDA]." *Ibid.* So not only did the State and Federal Governments regulate the same conduct; they did so in different ways.

Still, the Supreme Court held there was no conflict. *See id.* at 573–81. The Court reasoned as follows:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express preemption provision for medical devices, . . . Congress has not enacted such a provision for prescription drugs. . . . Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id. at 574–75 (citations omitted). Simply put, "Congress did not regard state tort litigation as an obstacle to achieving its purposes." *Id.* at 575.

Thus, *Wyeth* foreclosed Wells Pharma's expansive theory of preemption in the specific context of the FDCA. The Court held that States could regulate concurrently with the Federal Government the same primary conduct related to drug safety and effectiveness in different ways without interfering with FDA oversight. If regulating the same primary conduct in different ways does not upset federal enforcement prerogatives, it follows *a fortiori* that regulating it in parallel ways does not either.

III

Wells Pharma's principal response is a single case: *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). But *Buckman* is not to the contrary.

A

In that case, plaintiffs brought state fraud claims against Buckman after sustaining injuries from FDA-approved bone screws. *Id.* at 343. They argued Buckman had made fraudulent representations to the FDA and those representations had induced the FDA to approve the bone screws. *Ibid.*

The Supreme Court held that the FDCA preempted these "state-law fraud-on-the-FDA claims." *Id.* at 348. The States had no role, the Supreme Court reasoned, in "[p]olicing fraud against federal agencies." *Id.* at 347. "To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character." *Ibid.* And the FDCA gave ample methods to "the FDA to punish and deter fraud against the Administration." *Id.* at 348.

On this front, *Buckman* picked up where prior cases had left off. For instance, in *In re Loney*, 134 U.S. 372 (1890), the Supreme Court held that States had no power to punish perjury committed before a federal tribunal. As the Court explained, "the power of punishing a witness for testifying falsely in a judicial proceeding belongs peculiarly to the government in whose tribunals that proceeding is had." *Id.* at 375. Otherwise, it might deter "witnesses" from feeling "able to testify freely before them" because of "fear of punishment" or other form of liability under "legislation of the state." *Ibid.* *Buckman* recognized similar concerns. "[F]raud-on-the-FDA claims" under state law, the Court reasoned, would "cause applicants to fear that their disclosures to the FDA" would "later be judged insufficient in state court." *Buckman*, 531 U.S. at 351. As a result, applicants would "'submit a deluge of

information that the [agency] neither wants nor needs, resulting in additional burdens on the [agency's] evaluation of an application,' and harmful delays in the agency process." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 604 (2011) (quoting *Buckman*, 531 U.S. at 351). That would "directly interfere[] with the operation of the federal program." *Ibid.* (discussing *Buckman*).

The problem in *Buckman* had nothing to do with state law mirroring federal requirements; the state law at issue was ordinary, generally applicable fraud. Instead, the problem in *Buckman* was that the claim "involve[d]" a "uniquely federal area[] of regulation," since it alleged only "fraud on a federal agency." *Whiting*, 563 U.S. at 604 (discussing *Buckman*). In other words, the plaintiffs in *Buckman*, just like the States in *Loney*, sought to wield state law to vindicate a wrong committed *against the Federal Government*. The plaintiffs were hurt by that wrongdoing only incidentally.

This case is different. No one here argues that Wells Pharma's wrongdoing was really committed against the Federal Government, like the fraud in *Buckman* or the perjury in *Loney*. Wells Pharma has not unfairly competed against the FDA, leading to some incidental harm to Zyla.

Moreover, Zyla is not policing the uniquely federal relationship between Wells Pharma and the FDA. So there is no reason to think that allowing Zyla's claims to proceed will "*directly interfere[]* with the operation of the federal program." *Whiting*, 563 U.S. at 604 (emphasis added). There is no sense in which any action "deemed appropriate by the Administration, will later be judged insufficient in state court." *Buckman*, 531 U.S. at 351. And Wells Pharma gives no reason to think allowing Zyla's claims to proceed would somehow "deluge" the FDA in unwanted "information"; result in harmful delays in the FDA's processing of applications; or deter applicants from seeking FDA approval. *Ibid.* In short, there is no reason to think

allowing these claims to proceed will in any sense upset any purposes and objectives of Congress whatsoever.

B

Wells Pharma points to certain language in *Buckman* about the preemptive effect of the FDCA's allocation of enforcement discretion to the Federal Government. But the Supreme Court's language, like all language, must be understood in context. And four aspects of that context make us doubt Wells Pharma's interpretation.

First, even *Buckman*'s most sweeping language fully accords with the analysis above when read in context: In context, *Buckman* holds that the FDCA's allocation of enforcement to the Federal Government forecloses non-federal actors from policing *wrongdoing against the Federal Government*. *See, e.g.*, *id.* at 348 ("The balance sought by the Administration can be skewed by allowing *fraud-on-the-FDA claims* under state tort law." (emphasis added)); *id.* at 349 ("The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected *fraud upon the Administration*." (emphasis added; footnote omitted)); *id.* at 350 ("State-law *fraud-on-the-FDA claims* inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (emphasis added)).

Second, any broader reading of *Buckman* would conflict with the Court's more recent pronouncements in *Wyeth v. Levine*. *Wyeth* permitted distinct state regulation under the FDCA. If that does not conflict with federal enforcement prerogatives, neither does parallel state regulation. *See supra*, at 14, 16.

Third, many federal statutes grant the Executive Branch extensive enforcement discretion.[8] But as we have explained, those statutes do not preclude parallel or non-parallel state regulation of the same conduct. If they were read to do so, the States' power over criminal and tort law would dissipate. *See supra*, Part II.B.2.

Fourth and finally, there is no way to maintain Wells Pharma's broad reading of *Buckman* while escaping these problems. *Buckman* cannot be artificially limited to cases where state law incorporates federal standards. *Buckman* itself was not such a case—rather the plaintiffs there sued under generally applicable tort law.

* * *

For the foregoing reasons, the district court's order granting Wells Pharma's motion to dismiss is REVERSED. Wells Pharma's cross-appeal of the denial of its motion for an award of attorney's fees is DISMISSED AS MOOT. The district court's order denying Zyla's motion for leave to amend is VACATED. And the case is REMANDED for further proceedings consistent with this opinion.

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[8] For this reason, 21 U.S.C. § 337(a) is beside the point. Section 337(a) only confers a cause of action upon the Federal Government to enforce the FDCA. That is necessary because otherwise the Federal Government's power to bring non-statutory actions to enforce federal law is unclear. *Cf., e.g.*, 3 JOSEPH STORY, COMMENTARIES ON THE CONSTITUTION OF THE UNITED STATES § 1274, at 154 (Boston, Hilliard, Gray & Co. 1833) (noting that the Federal Government has a right to sue only if Congress statutorily authorizes it). Section 337(a) says nothing about the States' authority to provide remedies for violations of state law. *See ARC Am. Corp.*, 490 U.S. at 103 (explaining that offering a state remedy for conduct that violates both state and federal law does not "affect remedies available under federal law" but merely offers a separate remedy under state law for violations of state law).

United States Court of Appeals

FIFTH CIRCUIT
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April 10, 2025

MEMORANDUM TO COUNSEL OR PARTIES LISTED BELOW

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

No. 23-20533 Zyla Life Sciences v. Wells Pharma
USDC No. 4:22-CV-4400

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 Wells Pharma of Houston, L.L.C. pay to Zyla Life Sciences, L.L.C. the costs on appeal. A bill of cost form is available on the court's website www.ca5.uscourts.gov.

Sincerely,

LYLE W. CAYCE, Clerk
Amanda M. Duroncelet
By:_____
Amanda M. Duroncelet, Deputy Clerk

Enclosure(s)

Ms. Nicole Bronnimann
Mr. Jeffrey S. Bucholtz
Mr. Aaron B. Craig
Mr. Robert Harrison Golden
Mr. Jeremy Thomas Grabill
Ms. Margaret Manning
Mr. Randall Nice
Mr. David Lee Patron