NO. _____

In the
Supreme Court of the United States

HOPE MEDICAL ENTERPRISES, INC.
DBA Hope Pharmaceuticals,
Petitioner,

v.

FAGRON COMPOUNDING SERVICES, LLC; JCB LABORATORIES, LLC; ANAZAOHEALTH CORPORATION; COAST QUALIFY PHARMACY, LLC,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

Joseph N. Akrotirianakis
Aaron Craig
KING & SPALDING LLP
633 W 5th Street
Suite 1600
Los Angeles, CA 90071

Matthew V.H. Noller
KING & SPALDING LLP
50 California Street
Suite 3300
San Francisco, CA 94105

Jeffrey S. Bucholtz
Counsel of Record
KING & SPALDING LLP
1700 Pennsylvania Ave. NW
Washington, DC 20006
(202) 737-0500
jbucholtz@kslaw.com

Counsel for Petitioner

January 16, 2024

QUESTION PRESENTED

Before Congress enacted the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, the States had the exclusive power to regulate drug sales within their borders. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). After the FDCA's enactment, States continued to exercise their historical power to regulate drug safety by passing statutes that prohibit the in-state sale of drugs that have not been approved under the FDCA by the federal Food and Drug Administration. Until recently, all courts had agreed that the FDCA does not preempt such state statutes. *E.g.*, *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354–56 (Fed. Cir. 2013).

The Ninth Circuit created a circuit split in *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (9th Cir. 2022), where it held that the FDCA preempts state drug-approval statutes even when there is no difference in the requirements of state and federal law. In the decision below, the Ninth Circuit followed *Nexus* to hold that the FDCA preempts the enforcement of state drug-approval statutes against an unapproved drug that is also undisputedly illegal under the FDCA.

The question presented is:

Whether the FDCA preempts state laws prohibiting the in-state sale of unapproved drugs whose sale is also prohibited as a matter of federal law by the FDCA.

RELATED PROCEEDINGS

Hope Med. Enters., Inc. v. Fagron Compounding Servs., LLC, No. 22-55173, 2023 WL 4758454 (9th Cir. July 26, 2023)

Hope Med. Enters., Inc. v. Fagron Compounding Servs., LLC, No. 21-55165, 2021 WL 5860886 (9th Cir. Dec. 10, 2021)

Hope Med. Enters., Inc. v. Fagron Compounding Servs., LLC, No. 2:19-cv-07748, 2021 WL 4963516 (C.D. Cal. Oct. 26, 2021)

Hope Med. Enters., Inc. v. Fagron Compounding Servs., LLC, No. 2:19-cv-07748, 2021 WL 753566 (C.D. Cal. Jan. 25, 2021)

Hope Med. Enters., Inc. v. Fagron Compounding Servs., LLC, No. 2:19-cv-07748, 2020 WL 3803029 (C.D. Cal. July 7, 2020)

CORPORATE DISCLOSURE STATEMENT

Petitioner Hope Medical Enterprises, Inc., d/b/a Hope Pharmaceuticals, is a privately owned corporation. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

TABLE OF CONTENTS

Appendix

Appendix F

Relevant Constitutional Provisions and Statutes

TABLE OF AUTHORITIES

Cases

Constitutional Provisions

Statutes

Regulations & Rules

Other Authorities

PETITION FOR WRIT OF CERTIORARI

Petitioner Hope Medical Enterprises, Inc., respectfully petitions for a writ of certiorari to review the judgment of the Ninth Circuit.

OPINIONS BELOW

The Ninth Circuit's decision (App.1–3) is available at 2023 WL 4758454. The Ninth Circuit's order denying rehearing en banc (App.130) is unpublished, as is the Ninth Circuit's order staying its mandate (App.131–32). The district court's post-trial findings of fact and conclusions of law (App.4–68) are available at 2021 WL 4963516. The district court's redacted order granting Hope's motion for a preliminary injunction (App.69–129) is available at 2020 WL 3803029.

JURISDICTION

The Ninth Circuit issued its decision on July 26, 2023, and denied rehearing on October 2, 2023. On December 17, 2023, Justice Kagan granted Hope's application to extend the deadline for this petition until January 16, 2024. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Relevant constitutional and statutory provisions are reproduced in the Appendix.

STATEMENT

A. Legal background

1. The decision below all but eliminates States' power to regulate the in-state sale of drugs that have

not been reviewed for safety or approved by any government body. At the Founding, however, that power belonged *exclusively* to the States. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). In 1906 Congress enacted its "first significant public health law," which "prohibited the manufacture or interstate shipment of adulterated or misbranded drugs." *Id.* Even then, though, the federal government did not review or approve drugs before sale. *Id.*

That changed in 1938 when Congress passed the Food, Drug, and Cosmetic Act with its "provision for premarket approval of new drugs." *Id.* The premarket approval requirement now appears in § 505 of the FDCA and provides that "[n]o person" may "introduce or deliver for introduction into interstate commerce any new drug" unless FDA has first "approv[ed]" an "application." 21 U.S.C. § 355(a). The premarket approval requirement "protect[s] the public health" by "assur[ing] the safety, effectiveness, and reliability of drugs." *Wyeth*, 555 U.S. at 567 (cleaned up).

2. The FDCA, like the 1906 Act before it, "supplemented" but did not override the "protection for consumers already provided by state regulation." *Id.* at 566. While expanding FDA's authority, Congress still "took care to preserve state law." *Id.* at 567. The original FDCA presumed that States would regulate drug sales alongside the federal government. *See* Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, ch. 675, § 304(d), 52 Stat. 1040, 1045 (1938) (providing that certain drugs "shall not be sold or disposed of contrary to the provisions of this Act *or the laws of any State* … in which sold" (emphasis added)). And when Congress amended the

prescription-drug provisions of the FDCA in 1962, it "added a saving clause, indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Wyeth*, 555 U.S. at 567 (quoting Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793). Congress has never enacted an express-preemption provision for state laws regulating prescription drugs. *Id.* at 574. State and federal drug regulations have thus "coexiste[d]" for the FDCA's entire 85-year history. *Id.* at 581.

In particular, most States have enacted laws that prohibit the in-state sale of a drug that has not received premarket approval from FDA or from an appropriate state agency.[1] And several States have "act[ed] within [their] historic[al] purview to regulate health and safety" by "authorizing private suits to enjoin the intrastate distribution, sale, and marketing

---

[1] Alaska Stat. § 17.20.110(a)(1); Ariz. Rev. Stat. § 32-1962; Ark. Code §§ 20-56-202(1)(E), 20-56-215(1); Cal. Health & Safety Code § 111550; Colo. Rev. Stat. § 12-280-131(1); Conn. Gen. Stat. § 21a-110; Fla. Stat. § 499.023; Ga. Code Ann. § 26-3-10; Haw. Rev. Stat. § 328-17; Idaho Code § 37-128; 410 Ill. Comp. Stat. 620/17; Ind. Code § 16-42-3-7; Iowa Code § 126.12; Kan. Stat. § 65-669a; Ky. Rev. Stat. Ann. § 217.075; Md. Code Ann., Health-Gen. § 21-223; Mich. Comp. Laws § 333.7402(1); Mo. Rev. Stat. § 196.105; Mont. Code Ann. § 50-31-311; Nev. Rev. Stat. § 585.490; N.J. Stat. Ann. § 24:6A-1; N.M. Stat. Ann. § 26-1-14; N.Y. Educ. Law § 6817(1)(a); N.C. Gen. Stat. § 106-135; N.D. Cent. Code § 19-02.1-16; Ohio Rev. Code Ann. § 3715.65; Or. Rev. Stat. § 689.135(13); 35 Pa. Cons. Stat. § 780-113(36); R.I. Gen. Laws § 21-31-16; S.C. Code Ann. § 39-23-70; Tenn. Code Ann. § 53-1-110; Tex. Health & Safety Code Ann. § 431.114; Vt. Stat. Ann. tit. 18, § 4065; Va. Code § 54.1-3421; Wash. Rev. Code § 69.04.570; Wyo. Stat. Ann. § 35-7-118; *see also* 10 Guam Code Ann. § 40117; P.R. Laws Ann. tit. 24, § 726.

of an unapproved drug." U.S. Br. as Amicus Curiae 16–17, *Athena Cosmetics, Inc. v. Allergan, Inc.*, 576 U.S. 1054 (2015) (No. 13-1379), 2015 WL 2457643 ("U.S. *Athena* Br.").

This case involves the drug-approval laws of five States: California, Connecticut, Florida, Tennessee, and South Carolina. California's "Sherman Law" provides that "[n]o person shall sell, deliver, or give away any new drug" unless (1) "[a] new drug application has been approved for it … under Section 505 of the [FDCA]" or (2) the California Department of Health Services "has approved a new drug or device application for that drug." Cal. Health & Safety Code § 111550(a)–(b). Connecticut prohibits the sale of "any new drug unless … an application with respect thereto has been approved under Section [505] of the [FDCA]." Conn. Gen. Stat. § 21a-110. Florida prohibits the in-state sale of "any new drug unless an approved application has become effective under s. 505 of the [FDCA] or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services." Fla. Stat. § 499.023. Tennessee prohibits the sale of "any new drug unless an application with respect to that drug has become effective under § 505 of the [FDCA]." Tenn. Code Ann. § 53-1-110. And South Carolina prohibits the sale of "any new drug" unless the relevant state agency approves the drug or "an application with respect thereto has been approved … under § 505 of the [FDCA]." S.C. Code Ann. § 39-23-70(a).

As part of the "long history of state common-law and statutory remedies against … unfair business practices," *California v. ARC Am. Corp.*, 490 U.S. 93,

101 (1989), these five States have also enacted consumer-protection laws that allow private litigants to sue based on violations of other state laws. Cal. Bus. & Prof. Code § 17200; Fla. Stat. §§ 501.203, 501.204, 501.211; Tenn. Code Ann. § 47-18-104; S.C. Code Ann. §§ 39-5-20, 39-23-70; Conn. Gen. Stat. § 42-110b. All five States' consumer-protection laws authorize suits to enforce the States' drug-approval laws. App.38, 40, 42–46 ¶¶ 24, 32, 38, 44, 50–51.

3. The FDCA contains an exception from § 505's premarket approval requirement for lawfully "compounded" drugs. 21 U.S.C. §§ 353a, 353b. Traditionally, "compounding" referred to a pharmacist's "combin[ing], mix[ing], or alter[ing] ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). The practice of pharmacy, like other professions, was traditionally the province of state, not federal, regulation, and until the early 1990s "FDA generally left regulation of compounding to the States." *Id.* at 361–62.

If not appropriately confined, however, "compounding" can become a fig leaf for the large-scale manufacturing of unapproved drugs. "FDA eventually became concerned" that "pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Id.* Following a 2012 "catastrophe" involving compounding—"a mass outbreak of deadly meningitis caused by contaminated compounded drugs"—Congress revisited the FDCA's compounding provisions, amending § 503A and enacting § 503B. *Nexus Pharms., Inc. v. Cent. Admixture Pharm. Servs.,*

Inc., 48 F.4th 1040, 1043 (9th Cir. 2022); 21 U.S.C. §§ 353a, 353b.

Sections 503A and 503B impose requirements for different kinds of compounding that, when satisfied, exempt a drug from premarket approval under § 505. Section 503A applies to traditional, patient-specific pharmacy compounding, while § 503B—the provision relevant here—governs "outsourcing facilities," which (unlike traditional compounders) may produce "'large quantities'" of standardized drugs, but only under limited circumstances justifying reliance on such an unapproved drug. App.17–18 ¶¶ 27–28 (quoting *Athenex Inc. v. Azar*, 397 F. Supp. 3d 56, 59 (D.D.C. 2019)).

Among other restrictions, "[s]ection 503B specifically limits the types of drugs that can be compounded at outsourcing facilities" using bulk drug substances (*i.e.*, a drum of the active ingredient): either (1) the "bulk drug substance" must "appear on … a list established by [FDA] identifying bulk drug substances for which there is a clinical need" for use by outsourcing facilities (known as the "503B bulks list"); or (2) the "drug compounded from such bulk drug substance" must "appear[] on the drug shortage list" created by FDA. App.18 ¶ 29 (cleaned up); 21 U.S.C. § 353b(a)(2).

A 503B facility cannot compound drugs "using bulk drug substances" unless it satisfies one of these two conditions. 21 U.S.C. § 353b(a)(2); *see Azurity Pharms., Inc. v. Edge Pharma, LLC*, 45 F.4th 479, 501 (1st Cir. 2022); *Athenex*, 397 F. Supp. 3d at 60. In this way, outsourcing facilities fill clinical gaps not met by commercially available, FDA-approved drugs, but do

not displace FDA-approved drugs. *See* FDA, Guidance for Industry: Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act ("503B Bulk Drug Substance Guidance"), at 4–6 (Mar. 2019), https://www.fda.gov/media/121315/download.

To further ensure that outsourcing facilities' unapproved drugs do not displace FDA-approved drugs, § 503B also forbids the compounding of drugs that are "essentially a copy" of approved drugs. 21 U.S.C. § 353b(a). Section 503B contains two distinct "essentially a copy" provisions. The first applies to compounded drugs made using a finished, FDA-"approved drug" as the starting point. *Id.* § 353b(d)(2)(A). This is called "sterile-to-sterile" compounding. *Athenex*, 397 F. Supp. 3d at 60. The other "essentially a copy" provision applies to compounded drugs that are made using "bulk drug substance[s]," rather than starting from a finished, FDA-approved drug product. 21 U.S.C. § 353b(d)(2)(B).

It is undisputed that only "bulk drug compounding"—not sterile-to-sterile compounding—is at issue in this case. *Hope Med. Enters., Inc. v. Fagron Compounding Servs., LLC*, 2021 WL 5860886, at *1 (9th Cir. Dec. 10, 2021); *see* 9th Cir. Supp. Excerpts of Record ("SER")-33 ¶ 13. Compounding from bulk drug substances poses greater threats to patients and the integrity of the FDA-approval process than sterile-to-sterile compounding, so Congress imposed greater restrictions on it, including a broader "essentially a copy" prohibition. 503B Bulk Drug Substance Guidance at 4–6. A compounded drug is "essentially a

copy" of an FDA-approved drug if it contains "a bulk drug substance that is a component of an approved drug," unless the 503B facility obtains a statement from "the prescribing practitioner" attesting that the compounded drug reflects a "change" to the copied drug that "produces for an individual patient a clinical difference." 21 U.S.C. § 353b(d)(2)(B). These attestations are known as "clinical difference" statements. App.19 ¶ 31.

Even after Congress amended § 503A and added § 503B to the FDCA in 2013, compounding continues to be actively regulated by the States. Section 503A explicitly reflects States' ongoing role in this area, directing FDA to enter into a memorandum of understanding with States regarding information-sharing and enforcement. 21 U.S.C. § 353a(b)(3)(B).[2] FDA recognizes States' ongoing role with respect to both 503A and 503B compounders. *See* FDA, *Compounding Information for States* (Mar. 22, 2023), https://www.fda.gov/drugs/human-drug-compounding/compounding-information-states; *see also* Drug Quality and Security Act, Pub. L. No. 113-54, § 107, 127 Stat. 587, 598 (2013) (requiring report on "the adequacy of State and Federal efforts to assure the safety of compounded drugs," including "a review of the State laws and policies governing pharmacy compounding" and "enforcement of State laws and policies"). And States continue to "regulate compounding practices as

[2] *See* FDA, *Memorandum of Understanding Addressing Certain Distributions of Compounded Drugs* (Oct. 10, 2022), https://www.fda.gov/drugs/human-drug-compounding/memorandum-understanding-addressing-certain-distributions-compounded-drugs.

part of their regulation of pharmacies." *W. States Med. Ctr.*, 535 U.S. at 361; *see, e.g.*, Cal. Code Regs. tit. 16, § 1735.2; Pew Charitable Trs., State Oversight of Drug Compounding (Feb. 2018), *available at* https://www.pewtrusts.org/en/research-and-analysis/reports/2018/02/state-oversight-of-drug-compounding.

4. Although the FDCA contains no preemption provision for state laws regulating prescription drugs, it does limit the class of plaintiffs who have standing to enforce it. The FDCA's standing provision states that all "proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). That provision reflects the fact "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment." *Wyeth*, 555 U.S. at 574.

But § 337(a) is not a preemption provision. Most obviously, it does not say anything about States' authority to enact or enforce their own laws. It was enacted in the same 1938 FDCA that, as discussed above, presumed the coexistence of state and federal drug regulations. Pub. L. No. 75-717, §§ 304(d), 307, 52 Stat. 1040, 1045–46. Indeed, Congress decided not to create a private right of action under the FDCA precisely *because* it "determined that widely available state rights of action provided appropriate relief for injured consumers" and "further consumer protection by motivating manufacturers to produce safe and effective drugs." *Wyeth*, 555 U.S. at 574. Consistent with that policy to preserve state drug regulations, the 1962 FDCA amendments added a saving clause that

disclaimed preemption absent a "direct and positive conflict," notwithstanding § 337(a). *Id.* at 567 (quoting Pub. L. No. 87-781, § 202, 76 Stat. at 793). And this Court has recognized that the FDCA contains no preemption provision for prescription drugs—which is no accident, given Congress's enactment of express preemption provisions applicable to over-the-counter drugs, class III medical devices, and other products covered by the FDCA. *Id.* at 574.

Section 337(a), therefore, does not prohibit States from enacting their own laws that borrow or parallel the FDCA's requirements as a matter of state law. *E.g.*, *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354–56 (Fed. Cir. 2013), *cert. denied*, 576 U.S. 1054 (2015) (mem.); *Hughes v. Bos. Sci. Corp.,* 631 F.3d 762, 774–75 (5th Cir. 2011); *Farm Raised Salmon Cases*, 175 P.3d 1170, 1181–84 (Cal. 2008), *cert. denied sub nom. Albertson's, Inc. v. Kanter*, 555 U.S. 1097 (2009) (mem.). The United States agrees, as the Solicitor General has explained in invitation briefs to this Court. U.S. *Athena* Br. 8–17; U.S. Br. as Amicus Curiae 8–20, *Albertson's*, 555 U.S. 1097 (No. 07-1327), 2008 WL 5151069 (U.S. *Albertson's* Br.). "Actions to enforce state laws that impose requirements identical to those under the FDCA are not actions to enforce the FDCA itself.... [E]ven when state-law claims are predicated on violations of the FDCA, they remain state-law claims." U.S. *Albertson's* Br. 12–13.

5. The Ninth Circuit split from this authority in *Nexus*. There, the plaintiff sued the defendant under the consumer-protection statutes of California and other States, alleging that the defendant violated those States' drug-approval laws by selling a drug that

had not been approved by FDA under § 505. *See* 48 F.4th at 1044. Although the defendant claimed its drugs were exempt from premarket approval under the FDCA's compounding provisions, the plaintiff alleged that the defendant did not lawfully compound its drugs, such that their sale was equally prohibited under state and federal law. *See id.*

The district court dismissed the plaintiff's complaint and the Ninth Circuit affirmed, holding that § 337(a) preempted the plaintiff's state-law claims. Even though the plaintiff sought to enforce *state* drug-approval statutes that mirrored the FDCA's requirements, the court held that § 337(a) impliedly preempts "state statute[s] which [themselves] rel[y] on the [FDCA]." *Id.* at 1046. Because the conduct that violates state drug-approval statutes also involves "noncompliance with FDA requirements," the court held that private enforcement of those state statutes is in fact private enforcement of the FDCA. *Id.*; *see id.* at 1049–50 (holding that enforcement of state drug-approval statutes "would amount to litigation of the alleged underlying FDCA violation" because the statutes "say[] in substance 'comply with the FDCA'").

In addition—and although the plaintiff alleged that the defendant's drug sales equally violated both state and federal law—the Ninth Circuit held that state drug-approval statutes conflict with "FDA's exclusive enforcement authority." *Id.* at 1048. Even when conduct violates both state and federal law, the court extended preemptive force to FDA's "enforcement discretion." *Id.* It held that States may not "facilitate enforcement" under state law "beyond

what the FDA has deemed appropriate" under federal law. *Id.*[3]

B. District court litigation

This petition follows a bench trial at which the district court made numerous detailed findings of fact. App.4–68. In their appeal below, respondents (collectively, "Fagron") did not challenge any of the district court's findings. *See generally* 9th Cir. Opening Br. As the case comes to this Court, therefore, those findings are undisputed.

1. Hope and Fagron are competitors in the marketplace for drugs containing sodium thiosulfate. App.5–6 ¶ 2. Hope sells "Sodium Thiosulfate Injection," an FDA-approved drug with sodium thiosulfate as the active pharmaceutical ingredient. App.19 ¶¶ 32–33.

Fagron owns and operates 503B facilities that, at the relevant times, mass-produced and sold an injectable sodium thiosulfate drug with the same concentration of sodium thiosulfate as Hope's Sodium Thiosulfate Injection. App.20, 24 ¶¶ 34, 53. Fagron's drug has not received premarket approval from FDA or any state agency. App.20 ¶ 35; App.34 ¶ 10. Fagron claimed to be exempt from the FDCA's premarket approval requirement because it "compound[s]" its drug. App.20 ¶ 36.

2. In this lawsuit, Hope alleged that Fagron violated the unfair-competition laws of California and four other States by selling unapproved drugs in violation of each State's drug-approval law. 9th Cir.

[3] The plaintiff in *Nexus* did not file a petition for certiorari.

Excerpts of Record ("ER")-652–57 ¶¶ 97–137. Hope's complaint alleged that all five States prohibit the sale of new drugs absent "an application approved by FDA under section 505 of the FDCA." ER-638 ¶ 45. It alleged that Fagron violated those laws "because [it] ha[s] not obtained the approval of FDA (or any other relevant regulatory authority)" for its "sodium thiosulfate drugs." ER-640 ¶ 55.

To head off Fagron's defense that it was "exempt" from state "drug-approval requirements," Hope also explained that Fagron did not satisfy the FDCA's compounding requirements. ER-634, 640–46. Hope's claims are thus based solely on Fagron's violation of *state* laws requiring pre-market approval by FDA or state agencies, but only in circumstances where federal law *also* independently prohibits the sale of Fagron's drug. ER-640 ¶ 55.

Shortly before trial, the parties jointly submitted a proposed Pretrial Conference Order containing various stipulated facts. SER-30. The parties stipulated that Fagron "ha[s] not applied for FDA approval of [its] compounded sodium thiosulfate drug." SER-32 ¶ 5. The parties also stipulated that "sodium thiosulfate" is a "component" of both Hope's Sodium Thiosulfate Injection and Fagron's unapproved drug. SER-33 ¶¶ 10–11. Finally, the parties stipulated that this case does not involve sterile-to-sterile compounding because Fagron "ha[s] always used bulk sodium thiosulfate and ha[s] never compounded [its] sodium thiosulfate drug product from a finished drug product." *Id.* ¶ 13.

3. The district court held a bench trial and issued a detailed decision, which concluded that Fagron's sale

of its unapproved sodium thiosulfate drug violated the five States' consumer-protection and drug-approval laws. In particular, the court found that Fagron's drug violated state drug-approval laws because it has not "been approved by the FDA under FDCA Section 505." App.38–39 ¶ 25 (cleaned up); *see* App.40–46 ¶¶ 32, 38, 44, 51. The court also considered and rejected, with extensive fact findings, Fagron's defense that its drug was exempt from premarket approval because it was lawfully compounded under § 503B of the FDCA. *See* App.33–37, 41–42, 44, 46, 48–56 ¶¶ 7–8, 11–19, 33, 39, 45, 52, 57, 61–73.

Despite its arguments at trial, Fagron has since conceded that its sodium thiosulfate drug is *not* exempt from premarket approval. It is undisputed in this Court that Fagron cannot lawfully sell its drug under *either* state *or* federal law without first receiving FDA approval under § 505. That is true for two independent reasons.

First, Fagron's drug is not exempt from premarket approval because it is undisputed that (a) sodium thiosulfate has never appeared on FDA's "503B bulks list" of bulk drug substances for which there is a clinical need for use by 503B facilities, and (b) Hope's Sodium Thiosulfate Injection has never appeared on FDA's drug shortage list. App.25 ¶ 57; 21 U.S.C. § 353b(a)(2).

Indeed, FDA has conclusively decided that sodium thiosulfate will not appear on the 503B bulks list. 87 Fed. Reg. 4240, 4249–50 (Jan. 27, 2022). On Fagron's behalf, a lobbying group for compounders nominated sodium thiosulfate for that list, arguing that there was a clinical need for its sodium thiosulfate drug as an

alternative to Hope's because Fagron's drug was potassium-free. *See id.* at 4249; D. Ct. Dkts. 285-5, 285-6, 285-11, 285-16; Fagron North America, Comment Letter on FDA Notice Regarding List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the FDCA (Sept. 29, 2020), *available at* https://downloads.regulations.gov/FDA-2018-N-3240-0256/attachment_1.pdf. At trial, Hope demonstrated that Fagron's claims regarding the presence or absence of potassium in the parties' competing drugs were pretextual. *E.g.*, App.26–27 ¶¶ 61–63. And in January 2022, FDA issued a final decision rejecting Fagron's claim. FDA explained that the potassium in Hope's drug posed no threat to patients and that Fagron's contention that certain patients had a clinical need for a potassium-free alternative was baseless. 87 Fed. Reg. at 4249–50. Given its finding of "no clinical need for compounding from the bulk drug substance sodium thiosulfate," FDA decided not to place sodium thiosulfate on the 503B bulks list. *Id.* Fagron did not challenge FDA's decision and has conceded that, as a result of FDA's decision, the FDCA prohibits the sale of its unapproved drug. ER-39; 9th Cir. Opening Br. 19, 31; 9th Cir. Opp. to Mot. to Stay Mandate 8.[4]

---

[4] Fagron has argued that it could use bulk sodium thiosulfate between October 30, 2019 and July 31, 2020, while sodium thiosulfate was on FDA's "list of Category 1 substances that [were] currently under evaluation" for the 503B bulks list. App.25 ¶ 58 (cleaned up). While § 503B prohibits the use of a bulk drug substance unless FDA has made an affirmative "clinical need" finding for it, 21 U.S.C. § 353b(a)(2)(A)(i), FDA's enforcement policy is generally not to take action against 503B facilities for using a bulk drug substance on the "Category 1" list while FDA

Second, Fagron's drug is not exempt from premarket approval because it is "essentially a copy" of Hope's Sodium Thiosulfate Injection. It is undisputed that "a component" of Fagron's drug is bulk sodium thiosulfate, which is also "a component of an approved drug," namely, Hope's Sodium Thiosulfate Injection. 21 U.S.C. § 353b(d)(2)(B); *see* App.34 ¶ 11; SER-33 ¶¶ 10–11. Yet Fagron sold its unapproved drug without ever obtaining the necessary "clinical difference" statements. 21 U.S.C. § 353b(d)(2)(B); App.27–30 ¶¶ 64–73; App.34–37 ¶¶ 12–18. Fagron did not challenge on appeal the district court's finding that it never obtained clinical difference statements, so that fact is established for purposes of this petition.

4. After FDA made its final determination not to place sodium thiosulfate on the 503B bulks list, Hope moved the district court to amend its judgment to reflect FDA's decision. ER-183. In response, Fagron "concede[d]" that FDA's decision prevented it from selling its drug under federal law without premarket approval. ER-39.

The district court enjoined Fagron from "distributing" its unapproved drug into the five States

---

evaluates whether a "clinical need" exists for its use under § 503B. App.25–26 ¶¶ 58, 60. Before October 30, 2019, however, sodium thiosulfate did not appear on either the 503B bulks list or the Category 1 list. App.26 ¶ 59. Fagron nonetheless used bulk sodium thiosulfate to make its drug for years before that date. Because Fagron's drug was not even arguably "exempted from the premarket approval requirement" at that time, either as a matter of law or FDA enforcement policy, App.37 ¶ 19, the Court need not consider FDA's Category 1 policy here.

at issue unless (1) "bulk sodium thiosulfate appears on" FDA's 503B bulks list, (2) "the drug compounded by [Fagron] from bulk sodium thiosulfate appears on FDA's 'drug shortage' list," or (3) "bulk sodium thiosulfate appears on FDA's 'Category 1' list." ER-3. The court also preserved an earlier injunction forbidding Fagron from selling its drug without "clinical difference" statements. ER-3–4.

The district court's injunction thus enforces state consumer-protection and drug-approval laws only in circumstances where state law is identical to federal law—where Fagron's drug is *not* exempt from premarket approval under § 505. In this way, the district court's decision took off the table Fagron's contention that it would conflict with federal law to enforce state drug-approval laws against drugs for which federal law does not require FDA approval.

C. The Ninth Circuit's decision

Fagron appealed the district court's judgment. It did not, however, challenge any of the court's findings. It argued exclusively that Hope's claims were preempted under *Nexus*. *See generally* 9th Cir. Opening Br.

The Ninth Circuit agreed with Fagron and reversed based entirely on *Nexus*. App.1–3. The Ninth Circuit did not question the district court's finding that state and federal law equally prohibit the sale of Fagron's unapproved drug. It simply held that, under *Nexus*, FDCA § 337(a)'s "prohibition on private enforcement and the doctrine of implied preemption bar the suit." App.3.

The Ninth Circuit denied rehearing, App.130, but stayed its mandate pending this petition, App.131–32.

REASONS FOR GRANTING THE PETITION

The Court should grant certiorari to review the Ninth Circuit's rule regarding FDCA preemption. The *Nexus* rule, which the Ninth Circuit held controlled this case, conflicts with the decisions of other federal courts of appeals and the California Supreme Court, with the United States' own views on FDCA preemption, and with this Court's precedent. Those conflicts necessitate this Court's review, and they are particularly intolerable here given that the Ninth Circuit's approach guts States' historical power to regulate drug safety and fair competition within their borders.

This case, moreover, provides the Court an unimprovable vehicle to decide the important question presented. As it comes to the Court, this case presents a pure question of law unencumbered by any disputed factual questions: Whether the FDCA preempts state laws that prohibit the exact same conduct as the FDCA. Because that question is important, subject to multiple splits of authority, and presented cleanly here, this is a classic case for certiorari. *See* S. Ct. R. 10.

I. The decision below and *Nexus* create multiple conflicts that this Court should resolve.

Consistent with this Court's precedent, decisions of other federal and state courts of appeals—and invitation briefs filed by the U.S. Solicitor General—agree that the FDCA does not preempt state laws, like the state drug-approval laws here, that borrow or parallel the FDCA's requirements. The Ninth Circuit's *Nexus* rule, which controlled the decision below,

conflicts with that authority by holding that the FDCA preempts state laws that prohibit the in-state sale of unapproved drugs that also cannot lawfully be sold under federal law. Those conflicts amply justify this Court's review.

A. The Ninth Circuit's rule conflicts with decisions from the Federal, Fifth, and First Circuits and the California Supreme Court.

Nexus was the first decision in which a federal or state appellate court held that the FDCA preempts state drug laws that impose the same requirements as the FDCA. Indeed, as *Nexus* itself acknowledges, other appellate courts have rejected *Nexus*'s approach to FDCA preemption.

The Ninth Circuit acknowledged in *Nexus* that its decision created a circuit split with the Federal Circuit's decision in *Athena*. *Nexus*, 48 F.4th at 1049–50. The plaintiff in *Athena* sued the defendant for violating California's Sherman Law, one of the state drug-approval statutes at issue in this case and in *Nexus*, by selling a drug that had not been approved by FDA. 738 F.3d at 1353. The defendant argued that § 337(a) preempted the Sherman Law because it "incorporates FDCA provisions" and thus "interferes with the FDA's discretionary authority." *Id.* at 1355. The Federal Circuit disagreed. "The fact that the [Sherman Law] parallels certain FDCA provisions," the court held, "does not mean that it does not implicate an historic state power that may be vindicated" by state law. *Id.* The court also held that the parallel nature of California's drug-approval

statute meant it was "not an obstacle to realizing federal objectives." *Id.* at 1356.

Nexus openly rejected *Athena*'s holding and rationale, and that acknowledged circuit split alone justifies certiorari. 48 F.4th at 1049–50. But *Nexus*'s disagreement with *Athena* further conflicts with the view of FDCA preemption expressed in the Solicitor General's brief opposing the *Athena* defendant's petition for certiorari. The Solicitor General explained "that the FDCA does not impliedly preempt [a] private civil action … to enforce state drug pre-market approval requirements that are substantively identical to those imposed by the FDCA." U.S. *Athena* Br. 8. States may "authoriz[e] private suits to enjoin the intrastate distribution, sale, and marketing of an unapproved drug" because the FDCA does not preempt state laws that "directly incorporate[] the federal new-drug application regulations." *Id.* at 9, 17. Such state laws fall "within the State's historic purview to regulate health and safety, as well as to protect against unfair competition," a "role" the FDCA "preserves … for the States." *Id.* at 17 (citation omitted). The *Nexus* rule directly conflicts with that position on FDCA preemption.

For the same reasons, the Ninth Circuit's rule conflicts with the California Supreme Court's decision in *Farm Raised Salmon*. That decision held that § 337(a) did not preempt a private lawsuit to enforce the Sherman Law's food-labeling provisions, which copy and incorporate the FDCA's food-labeling requirements. 175 P.3d at 1175–76, 1181–84. The California Supreme Court rejected the argument that the parallel nature of the state-law claims meant the

plaintiff was really suing under the FDCA itself: "That the Sherman Law imposes obligations identical to those imposed by the FDCA," the court explained, "does not substantively transform plaintiffs' action into one seeking to enforce federal law." *Id.* at 1181. The United States, as in *Athena*, endorsed this reasoning before this Court, explaining that the parallel nature of the state laws at issue did not justify disregarding those state laws and treating the action as one improperly brought under the FDCA: "Actions to enforce state laws that impose requirements identical to those under the FDCA are not actions to enforce the FDCA itself.... [E]ven when state-law claims are predicated on violations of the FDCA, they remain state-law claims." U.S. *Albertson's* Br. 12–13.

The United States thus rejected the exact theory of FDCA preemption that *Nexus* and the decision below adopted. It is anomalous to hold—in the name of protecting FDA's authority—that the FDCA bars States from enacting laws that parallel or incorporate the FDCA when the United States has twice told this Court that States retain that authority. *See Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 336 (2011) (rejecting preemption argument where the United States did not view state law as an obstacle, because the relevant federal agency "is 'uniquely qualified' to comprehend the likely impact of state requirements" (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000)); *see also Wyeth*, 555 U.S. 576–77 (explaining that the Court "attend[s] to an agency's explanation of how state law affects the regulatory scheme" because agencies "have a unique understanding of the statutes they administer and an attendant ability to make informed determinations

about how state requirements may pose an 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress'").

Nexus and the decision below also conflict with Fifth Circuit cases holding that FDCA § 337(a) does not preempt state-law claims that depend on proving an FDCA violation. *Spano ex rel. C.S. v. Whole Foods, Inc.*, 65 F.4th 260, 263–65 (5th Cir. 2023); *Bass v. Stryker Corp.*, 669 F.3d 501, 514 (5th Cir. 2012); *Hughes*, 631 F.3d at 774–75. It is thus well-established in the Fifth Circuit that § 337(a) does "not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Spano*, 65 F.4th at 265 (citing *Hughes*, 631 F.3d at 775). When "a plaintiff can show that the FDA-approved processes and procedures were not followed, and that the injury was caused by this deviation, the plaintiff's claim will be parallel" to rather than conflict with the FDCA. *Bass*, 669 F.3d at 512.

In this case in particular, there is no possible conflict between state and federal law. It is now undisputed that Fagron's drug cannot lawfully be sold under *either* state *or* federal law. In these circumstances, where state and federal law impose the exact same requirements, there can be no conflict between those laws. *E.g.*, *California v. Zook*, 336 U.S. 725, 735 (1949) (finding "no conflict," and therefore no preemption, when a "state statute makes federal law its own"); *Athena*, 738 F.3d at 1356. Nor is there any potential conflict between Hope's claims and FDA's authority to interpret or enforce the FDCA, because Fagron *concedes* that FDA's final decision not to place sodium thiosulfate on the "503B bulks list" renders

Fagron's drug illegal under the FDCA. There is no "interpretation" of the FDCA involved in that decision, App.3 (quoting *Nexus*, 48 F.4th at 1050), because there is nothing to interpret—you just have to look at the lists. And there is no risk of a court taking a different position than FDA, since the lists reflect decisions that FDA has already made.[5]

The First Circuit recently reached the same conclusion in a case arising under the Lanham Act. *Azurity*, 45 F.4th at 499–502. The plaintiff there claimed the defendant violated the Lanham Act by representing that its compounded drug satisfied FDCA § 503B even though it contained a bulk drug substance that did not appear on the 503B bulks list. *Id.* at 495. The defendant argued that § 337(a) precluded that claim because it required adjudicating whether it was complying with the FDCA, but the First Circuit disagreed. It held that the plaintiff sought "to enforce the Lanham Act, not the FDCA or its regulations." *Id.* at 500 (quoting *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 117, 120 (2014)). And "the adjudication of [the plaintiff's] claim simply require[d] a court to ascertain whether a particular drug appears on either the [503B bulks list], or on the drug shortage list," a straightforward determination that could not possibly "conflict" with "FDA policy discretion." *Id.* at 501–02 (cleaned up).

---

[5] This case thus does not present any question concerning whether substantively parallel state laws can nonetheless be deemed to "conflict" with federal law based on the potential for those laws to be interpreted or enforced in a way that a federal agency disagrees with. *Cf. Kansas v. Garcia*, 140 S. Ct. 791, 806–07 (2020); *infra* at 28.

That reasoning applies with full force to claims like Hope's. But as the decision below held, *Nexus* requires preemption in the exact circumstances *Azurity* held did *not* support preclusion. The *Nexus* rule thus creates a split with the First Circuit as well.

B. The Ninth Circuit's rule conflicts with this Court's precedent.

This Court's precedent confirms that *Nexus* erred by rejecting the majority approach to FDCA preemption. That further supports this Court's review.

Because the FDCA has no express preemption provision for prescription drugs, *Wyeth*, 555 U.S. at 574, *Nexus* and the decision below rest on implied preemption. There are two types of implied preemption: field preemption and conflict preemption. *See Kansas v. Garcia*, 140 S. Ct. 791, 801 (2020). And field preemption is a non-starter here, as this Court made clear in *Wyeth* that the FDCA does not occupy the field of prescription-drug regulation. 555 U.S. at 575. So the FDCA can preempt state drug-approval statutes only if those statutes *conflict* with the FDCA, either because it is "impossible" for defendants to comply with both the FDCA and state drug-approval statutes or because state drug-approval statutes "create[] an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wyeth*, 555 U.S. at 563–64 (cleaned up); *see Garcia*, 140 S. Ct. at 806. It is obviously possible for a defendant like Fagron to comply with both the FDCA and state drug-approval laws, and neither *Nexus* nor the decision below suggested otherwise. Those decisions thus depend

entirely on implied "purposes and objectives" preemption.

But those decisions never identify *any* actual conflict between the FDCA's requirements and state drug-approval statutes. This Court has long recognized that state statutes may borrow federal regulatory requirements without triggering preemption. In *Zook*, for example, the Court upheld a California statute prohibiting motor carriers from selling transportation without a federal or California permit. The Court held that when a "state statute makes federal law its own" in this way, there is "no possibility of [a] conflict" between state and federal law, and thus no preemption. 336 U.S. at 735; *accord Gilbert v. Minnesota*, 254 U.S. 325, 331 (1920); *Asbell v. Kansas*, 209 U.S. 251, 256–58 (1908); *cf. Arizona v. United States*, 567 U.S. 387, 402 (2012) ("a State may make violation of federal law a crime," unless federal law occupies the field). Conflict preemption without a *conflict* is an oxymoron.

There is no basis in this Court's precedent to adopt a different rule for the FDCA. To the contrary, the Court held in *Wyeth* that the FDCA reflects an intent to *preserve* rather than preempt state drug laws. 555 U.S. at 573–81. There, the Court held that state law "offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 579. That was true, the Court held, even though the plaintiff's state-law claims could require or induce a drug manufacturer to put a "stronger warning" on its label than the label approved by FDA. *Id.* at 573–74. The long history of coexistence between the FDCA and state drug

regulation convinced the Court that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575.

In particular, the Court found it important that Congress has never enacted an express preemption provision for prescription drugs, something Congress "surely would have" done if it "thought state-law suits posed an obstacle to its objectives." *Id.* at 574. Instead, Congress "wrote a pre-emption clause that applies only to medical devices." *Id.* (cleaned up). And even that preemption clause makes clear that state medical device laws are *not* preempted if they impose the same requirements as the FDCA; only state requirements that are "different from, or in addition to" the FDCA's requirements are preempted. 21 U.S.C. § 360k(a)(1). As a result, this Court has held that the express preemption provision does not "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *accord Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

It necessarily follows that such "parallel" state laws are not impliedly preempted either. If the FDCA impliedly preempted *all* state laws regarding products regulated under the FDCA, even state laws that parallel the FDCA's requirements, then the FDCA's express preemption provisions would serve no purpose. *See Corley v. United States*, 556 U.S. 303, 314 (2009) (discussing the "basic interpretive canon[] that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or

superfluous, void, or insignificant" (cleaned up)). And it would undermine Congress's decision to craft express preemption provisions for some products but *not* for prescription drugs to allow *implied* preemption to nullify a *broader* set of state prescription-drug laws—those that parallel federal law—than the laws that Congress subjected to *express* preemption. Given *Wyeth*'s holding that even *non-parallel* state-law claims regarding prescription drugs generally do not conflict with federal law, it would make no sense to hold that *parallel* state-law claims pose such a conflict.

The Ninth Circuit's contrary holding in *Nexus* and the decision below reflects the same "untenable interpretation of congressional intent" that *Wyeth* rejected. 555 U.S. at 573.[6] Despite not identifying any conflict between the requirements of state drug-approval statutes and the FDCA, the Ninth Circuit in *Nexus* found a conflict between those state statutes and "FDA's exclusive enforcement authority." 48 F.4th at 1048. In fact, *Nexus* went so far as to hold that FDA's mere "enforcement *discretion*" has preemptive force, such that States may not prohibit under state law drug sales that *also* violate federal law, merely because FDA might not elect to use its own resources to take enforcement action against those illegal sales. *Id.* (emphasis added). But *Wyeth* held both that FDA's authority over prescription drugs is *not* "exclusive" and that FDA has no power under the FDCA "to pre-empt state law directly." 555 U.S. at 575, 576. To the contrary, because FDA "has limited resources to

[6] *Nexus* even cited, with evident approval, academic criticism of *Wyeth*'s holding. 48 F.4th at 1047 & n.48.

monitor the … drugs on the market," the Court concluded that Congress viewed state law as providing a "complementary form of drug regulation." *Id.* at 578.

In addition, this Court recently held that "the possibility that federal enforcement priorities might be upset" by enforcement of non-conflicting state law "is not enough" for implied conflict preemption. *Garcia*, 140 S. Ct. at 807. That is because "[t]he Supremacy Clause gives priority to 'the Laws of the United States,' not the criminal law enforcement priorities or preferences of federal officers." *Id.* (quoting U.S. Const., art. VI, cl. 2).

Therefore, as the United States has explained, "[n]o conflict with a supposed FDA position … can be inferred from the absence of FDA enforcement or other regulatory action." U.S. *Athena* Br. 10. If a state-law suit would require a court to reject an "affirmative FDA decision" that was already made, that suit may conflict with federal law. *Id.* at 10–11. So, for example, if FDA has approved a drug, a plaintiff may not bring a lawsuit challenging the approval on the ground that the defendant defrauded FDA into granting approval. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347–48 (2001); *see Garcia*, 140 S. Ct. at 807 (recognizing that the claim in *Buckman* "threatened serious disruption of the sensitive and highly technical process of approving medical devices"); *Wyeth*, 555 U.S. at 656 n.3 (holding that *Buckman* applies to "fraud-on-the-agency claims," not "state regulation of health and safety"). But this case is the opposite of an attempt to use state law to challenge an FDA decision to approve a drug—the whole point of Hope's state-law claims is that Fagron's drug is unapproved. Nor has

FDA ever decided that Fagron's unapproved drug was exempt from premarket approval. To the contrary, the only affirmative action FDA has taken with respect to Fagron's drug was to decide that it *can't* lawfully be compounded under § 503B. *See* 87 Fed. Reg. at 4249–50. Hope's lawsuit is, therefore, perfectly consistent with federal law.

The FDCA's standing provision, § 337(a), does not alter this conclusion. Although that provision bars private enforcement *of the FDCA*, *see Buckman*, 531 U.S. at 352, this Court has recognized that a claim under a statute other than the FDCA does not constitute private enforcement of the FDCA just because the claim would require litigating whether the defendant's conduct violated the FDCA. *See POM Wonderful*, 573 U.S. 102; *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804 (1986).

In *POM Wonderful*, this Court held that § 337(a) does not preclude Lanham Act claims that are based on FDCA violations. The Ninth Circuit had held—consistent with the rule it later adopted in *Nexus*—that "a Lanham Act claim may not be pursued if the claim would require litigating whether [the defendant's] conduct violates the FDCA," because that would be an improper attempt "to enforce the FDCA or its regulations." *Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1175–76 (9th Cir. 2012). This Court unanimously reversed, holding that a suit "to enforce the Lanham Act" is not a suit to enforce "the FDCA or its regulations" even if it requires litigating issues under the FDCA. 573 U.S. at 117. Although *POM Wonderful* addressed preclusion of federal law, similar "principles" apply to preemption of state law.

Id. at 111–12. Indeed, *POM Wonderful* relied on *Wyeth* to hold that the "absence" of a "textual provision" in the FDCA "disclos[ing] a purpose to bar unfair competition claims" had "special significance because the Lanham Act and the FDCA have coexisted since the passage of the Lanham Act." *Id.* at 113. The same is true of the FDCA and state drug laws, which have "coexiste[d]" for the FDCA's entire history. *Wyeth*, 555 U.S. at 581. *POM Wonderful* thus compels the conclusion that a suit to enforce state drug laws, even if they incorporate or parallel the FDCA's requirements, is not a suit "to enforce the … FDCA." *POM Wonderful*, 573 U.S. at 117.

This Court's decision in *Merrell Dow* supports the same conclusion. There, the Court held that "the presence of a claimed violation of the [FDCA] as an element of a state cause of action" does not "confer federal-question jurisdiction." 478 U.S. at 814. That necessarily means a suit to enforce a state law that incorporates or parallels FDCA requirements is not a suit to enforce the FDCA. If the parallel nature of a state law justified looking through that state law and treating a suit as one to enforce the FDCA itself, then the suit would "arise under" the FDCA as "the law that creates the cause of action." *Id.* at 808 (quotation marks omitted).

Nexus's holding that state-law unfair-competition suits to enforce state drug-approval statutes constitute improper "enforcement" of the FDCA, 48 F.4th at 1048–50, thus conflicts with *POM Wonderful* and *Merrell Dow*. Indeed, *Nexus* relied on a Ninth Circuit Lanham Act decision that turned on the very theory *POM Wonderful* rejected: that "exclusive

government enforcement authority under the FDCA" precludes "private action[s] brought under the Lanham Act" if they require litigating issues under the FDCA. *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924–25 (9th Cir. 2010); *see Nexus*, 48 F.4th at 1048 (relying on *PhotoMedex*); *Azurity*, 45 F.4th at 502 n.11 (recognizing that *POM Wonderful* overruled *PhotoMedex*). *Nexus*'s reliance on a Lanham Act case that *POM Wonderful* overruled confirms that the Ninth Circuit's FDCA preemption rule is inconsistent with *POM Wonderful*.

II. This case is an ideal vehicle to address an important question about States' power to regulate drug safety within their borders.

These conflicts are particularly untenable given the importance of the question presented. Since the Founding, States have had power to regulate the in-state sale of drugs—and in particular drugs that have not been reviewed or approved by any governmental body—for health, safety, and fair-competition reasons. *Wyeth*, 555 U.S. at 566. States also have a "long history" of regulating "unfair business practices." *ARC Am.*, 490 U.S. at 101.

As this case demonstrates, *Nexus* nullifies those historical state powers by holding that the FDCA bars *all* claims under state drug-approval laws, even when the state law prohibits the *same conduct* as the FDCA. That is not conflict preemption under any recognized definition. Instead, *Nexus* enacts a tacit form of *field* preemption—a rule that the FDCA categorically prohibits States from legislating with respect to matters addressed by the FDCA. *See Nexus*, 48 F.4th at 1047–48 & n.48 (citing article criticizing *Wyeth* and

arguing for field preemption of state drug laws). *Nexus*'s rule, if applied nationwide, would invalidate drug-approval laws enacted by most States, plus an untold number of other state drug-safety laws. *Supra* note 1. Indeed, *Nexus* is already having that effect, as defendants across the country have begun arguing that the FDCA preempts state drug-approval laws. *See, e.g.*, *Novo Nordisk, Inc. v. Brooksville Pharms. Inc.*, 2023 WL 7385819, at *2–3 (M.D. Fla. Nov. 8, 2023); *Zyla Life Scis., LLC v. Wells Pharma of Houston, LLC*, 2023 WL 6301651, at *4 n.4 (S.D. Tex. Sept. 27, 2023), *appeal docketed*, No. 23-20533 (5th Cir. Oct. 31, 2023); *Eli Lilly & Co. v. Revive Rx, LLC*, 2023 WL 8936731, at *1 (S.D. Tex. Dec. 27, 2023).

That represents an extraordinary intrusion into state authority. It was not until 1906 that the federal government assumed any role in regulating drug sales, and not until 1938 that Congress passed the FDCA. *Wyeth*, 555 U.S. at 566. And if one thing about the FDCA is clear, it is that it does *not* occupy the field of drug safety. *See id.* at 575 ("Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."). Congress itself provided that the FDCA does not preempt the field by enacting a saving clause in the 1962 amendments. *Id.* at 567; *see* Pub. L. No. 87-781, § 202, 76 Stat. at 793. And Congress has never enacted a preemption provision for state regulation of prescription drugs. *Wyeth*, 555 U.S. at 567, 574. As this Court held in *Wyeth*, that history shows that Congress sought to preserve non-conflicting "state rights of action" alongside the FDCA and "to tolerate whatever tension there is between them." *Id.* at 574–75 (cleaned up). By holding otherwise, the *Nexus* rule undermines States'

"historic purview to regulate health and safety" and "to protect against unfair competition." U.S. *Athena* Br. 17.

This Court has previously recognized the importance of this issue by inviting the Solicitor General to file amicus briefs in *Athena* and *Farm Raised Salmon*. The Solicitor General's briefs in those cases addressed the same question presented here and argued that the FDCA does not preempt state drug-approval statutes. U.S. *Athena* Br. 8–17; U.S. *Albertson's* Br. 8–20. The Solicitor General recommended denial, but only because the appellate courts there had correctly *rejected* preemption, which did "not conflict with any decision of this Court or a federal court of appeals." U.S. *Albertson's* Br. 8; *accord* U.S. *Athena* Br. 8–9 (recommending denial because "[t]he court of appeals correctly held that the FDCA does not impliedly preempt this private civil action under California law to enforce state drug pre-market approval requirements that are substantively identical to those imposed by the FDCA," a holding that was "consistent with" the decisions of "lower courts" and "this Court's precedents"). Here, in contrast, the Ninth Circuit erroneously found preemption, which conflicts with *Athena*, *Farm Raised Salmon*, and the Solicitor General's briefs in those cases on a tremendously important issue. That decision cries out for this Court's review.

Nexus and the decision below also highlight the broader problems that Justices have identified with implied "purposes and objectives" preemption. *See, e.g.*, *Garcia*, 140 S. Ct. at 807–08 (Thomas, J., joined by Gorsuch, J., concurring) (arguing that the Court

"should explicitly abandon our 'purposes and objectives' pre-emption jurisprudence" because it "impermissibly rests on judicial guesswork about 'broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not contained within the text of federal law'" (quoting *Wyeth*, 555 U.S. at 587 (Thomas, J., concurring in the judgment))); *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1907–08 (2019) (plurality op. of Gorsuch, J., joined by Thomas and Kavanaugh, JJ.) (questioning doctrine of obstacle preemption because "the Supremacy Clause" cannot "be deployed … to elevate abstract and unenacted legislative desires above state law"). Although the FDCA's text expresses no intent to preempt state laws regulating prescription drugs, *Nexus* and the decision below found preemption based on little more than "a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in the judgment in part and dissenting in part) (cleaned up). Even *Nexus* recognized this problem, *see* 48 F.4th at 1045 ("The notion that preemption may be 'implied' at all seems oxymoronic, in light of the well-established rule that a 'clear expression' of congressional intent is required to overcome the 'presumption' against implied preemption."), before nonetheless proceeding to eliminate a vast area of traditional state regulatory authority.

This case, moreover, offers a perfect vehicle to address the important question presented. Whether the FDCA preempts state drug-approval statutes that prohibit the exact same conduct as the FDCA is a pure question of law that the Ninth Circuit decided on

purely legal grounds. And that question is presented cleanly here. Fagron did not challenge (and the Ninth Circuit did not question) any of the district court's post-trial findings, so there are no disputed factual questions that could obstruct the Court's review. And because Fagron has conceded that it cannot lawfully sell its drug under the FDCA, this case would not require the Court to address the question whether States may prohibit drug sales that the FDCA allows. All this Court need decide is whether the FDCA bars States from prohibiting the sale of unapproved drugs whose sale the FDCA also prohibits. The Court will never have a better vehicle for deciding that critical question.

CONCLUSION

This Court should grant the petition for certiorari.

Respectfully submitted,

Joseph N. Akrotirianakis
Aaron Craig
KING & SPALDING LLP
633 W 5th Street
Suite 1600
Los Angeles, CA 90071

Matthew V.H. Noller
KING & SPALDING LLP
50 California Street
Suite 3300
San Francisco, CA 94105
(415) 318-1200

Jeffrey S. Bucholtz
Counsel of Record
KING & SPALDING LLP
1700 Pennsylvania Ave. NW
Washington, DC 20006
(202) 737-0500
jbucholtz@kslaw.com

Counsel for Petitioner

January 16, 2024