No. 23-788

IN THE
Supreme Court of the United States

HOPE MEDICAL ENTERPRISES, INC.
D/B/A HOPE PHARMACEUTICALS,

Petitioner,

v.

FAGRON COMPOUNDING SERVICES, LLC;
JCB LABORATORIES, LLC;
ANAZAOHEALTH CORPORATION;
COAST QUALITY PHARMACY, LLC,

Respondents.

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

BRIEF IN OPPOSITION

KEITH J. WESLEY
ELLIS GEORGE LLP
2121 Avenue of the Stars
Suite 3000
Los Angeles, CA 90067
(310) 274-7100

CHRISTOPHER LANDAU
Counsel of Record
ELLIS GEORGE LLP
1155 F Street N.W.
Suite 750
Washington, DC 20004
(202) 249-6900
clandau@ellisgeorge.com

April 12, 2024

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, respondents state as follows:

Fagron N.V., a publicly held company, is the sole member/shareholder of Fagron B.V., which in turn is the sole member/shareholder of Fagron Holding USA, LLC, which in turn is the sole member/shareholder of respondents Fagron Compounding Services, LLC, JCB Laboratories, LLC, and AnazaoHealth Corporation. Respondent AnazaoHealth Corporation is the sole member/shareholder of respondent Coast Quality Pharmacy, LLC.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Rules

Other Authorities

INTRODUCTION

This case begins and ends with the simple point that the federal Food, Drug, and Cosmetic Act of 1938 (FDCA) provides that, subject to a limited exception not relevant here, "all … proceedings … to restrain violations … of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). As the Ninth Circuit recognized, a private lawsuit predicated on alleged FDCA violations, even if ostensibly based on state law, is necessarily a proceeding to restrain such alleged violations, and is thus prohibited by that provision.

In a nutshell, petitioner Hope Pharmaceuticals, a drug company, brought this ostensible state-law proceeding to stop respondents Fagron Compounding Services, LLC *et al.* (collectively Fagron) from selling certain compounded drug products that competed with Hope's drugs. According to Hope, such sales violated five States' drug-approval laws, and hence those States' unfair-competition laws, because Fagron's compounded drug products were not approved by either the federal Food and Drug Administration (FDA) or state regulators. But neither state nor federal regulators have created a regulatory regime that either authorizes or requires approval of compounded drug products, because the whole point of compounding is to provide an alternative for patients for whom an approved drug is either inappropriate or unavailable. *See generally Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61 (2002) (describing compounding); *Nexus Pharms., Inc. v. Cent. Admixture Pharm. Servs., Inc.*, 48 F.4th 1040, 1042-43 (9th Cir. 2022) (same).

The FDCA thus establishes a comprehensive scheme governing compounding, and provides that the compounded drug products authorized thereby are exempt from approval as drugs. *See* 21 U.S.C. §§ 353a(a), 353b(a) (FDCA Sections 503A and 503B). Hope thus based this case on the theory that sales of Fagron's compounded drug products required approval because they violated the FDCA's drug compounding requirements. In summarizing the "Nature of the Action" in its operative complaint, Hope stated that this lawsuit seeks "to stop [Fagron] from unlawfully manufacturing and selling unapproved new drugs *under the false guise that they are engaged in lawful 'compounding.'*" Supp. App. 2a (emphasis added). And why was Fagron's compounding allegedly unlawful? According to Hope, precisely because Fagron violated the FDCA's compounding provisions, Sections 503A and 503B, *see* Supp. App. 14-23a—not any parallel state compounding requirements, but the FDCA's compounding requirements themselves.

Hope thus argued below that it was "likely to prevail on its claims" because "[Fagron's] compounding practices violate FDCA Sections 503A and 503B." Supp. App. 62a (capitalization modified; bolding removed). The district court, in turn, expressly recognized that "Hope's state-law consumer protection claims are *predicated on* [Fagron's] alleged violations of [FDCA] Sections 503A and 503B," App. 80 (emphasis added); App. 101 (same), and ruled in Hope's favor only after holding a bench trial on whether Fagron had violated these FDCA provisions, *see* App. 10-38. Indeed, because everyone agreed that drug products generally require approval unless they qualify as lawful compounds under the FDCA, *this*

entire dispute hinged on whether Fagron's drug products qualified as lawful compounds under the FDCA.

But the whole point of the FDCA's prohibition on private enforcement is that courts are not supposed to adjudicate private claims alleging FDCA violations. And that is precisely why the Ninth Circuit held, both in this case and in *Nexus*, 48 F.4th 1040, that such claims—even if framed as state-law claims—are preempted. "[T]he FDCA's prohibition on private enforcement bars a drug manufacturer from suing another drug manufacturer for economic harm '*because the defendant violated the FDCA*.'" App. 3 (quoting *Nexus*, 48 F.4th at 1050; emphasis added). It is not up to judges and/or juries to determine that there has been a violation of the FDCA before the FDA itself has made such a determination.

Precisely because Hope's claims in this case are "predicated on" alleged FDCA violations, App. 80, 101, the conflict in authority alleged by Hope is illusory. In sharp contrast to this case, none of the authorities identified by Hope as supporting its position involved ostensible state-law claims predicated on a violation of the FDCA itself, as opposed to parallel state-law provisions. Whether Hope could have pursued state-law claims independent of federal law presents an interesting academic question wholly divorced from the reality of how Hope framed and litigated this case. From the beginning, as both the district court and the Ninth Circuit recognized, this case has been about alleged violations of *the FDCA's* compounding requirements, not any parallel state compounding requirements. It is far too late in the day for Hope

now to deny that its claims are predicated on alleged FDCA violations.

In any event, wholly apart from the merits and the absence of any circuit split, this case presents a poor vehicle for addressing the question presented. This case seeks only injunctive and declaratory relief; Hope expressly disclaimed its original request for money damages. But after the district court entered final judgment below, the FDA barred Fagron from making the compounds at issue here. Accordingly, this dispute is over: in light of the FDA's decision, Fagron can no longer do what this lawsuit seeks to prevent it from doing. Hope is thus requesting nothing more than an impermissible advisory opinion, and this Court could not reach the question presented without first wandering through a mootness thicket.

COUNTERSTATEMENT OF THE CASE

A. Background

Respondent Fagron is engaged in the business of compounding drug products. A compounded drug product differs in fundamental ways from a conventional drug. As this Court has explained, "[d]rug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to an individual patient." *Thompson*, 535 U.S. at 360-61. Thus, by definition, a compounded drug product is not subject to premarket approval—the whole point of compounding is to address a specific medical need for which there is no approved drug. *See, e.g.*, *Nexus*, 48 F.4th at 1042. Accordingly, as Hope acknowledges, "[t]he FDCA contains an exception from [its] premarket approval requirement for lawfully

'compounded' drugs." Pet. 5 (citing 21 U.S.C. §§ 353a, 353b).

As relevant here, Fagron manufactured and distributed compounds featuring sodium thiosulfate as the active ingredient. Those compounds were especially effective for kidney care because they did not contain potassium. Potassium accumulation is a significant problem for a large subset of renal patients.

Petitioner Hope is a conventional drug manufacturer: it makes and sells drugs subject to federal and/or state premarket approval. After Fagron began production and distribution of its sodium thiosulfate compound, Hope obtained FDA approval to sell a sodium thiosulfate drug to treat cyanide poisoning. *See* Pet. 12. In contrast to Fagron's compound, however, Hope's approved drug contains potassium. Although Hope's drug is not approved for kidney treatment, the drug is widely used off-label for such treatment in competition with Fagron's sodium thiosulfate compounds.

B. Proceedings Below

Hope filed this lawsuit against Fagron in September 2019, seeking to block Fagron from distributing or selling its sodium thiosulfate compounds in five different States (California, Connecticut, Florida, South Carolina, and Tennessee). The complaint, as amended, alleged that Fagron's distribution and sales of those compounds violated those States' unfair competition laws because Fagron's drug products were not approved, and required such approval because they did not satisfy the FDCA's drug compounding requirements. *See* Supp. App. 2a, 5-8a, 12-23a. Although Hope originally

requested money damages, it subsequently disavowed that request and sought only declaratory and injunctive relief.

At the outset, Hope sought a preliminary injunction to stop sales of Fagron's challenged compounds in the five States at issue while this litigation was pending. *See* Supp. App. 37-75a. As part of its required showing of likelihood of success on the merits, Hope argued that it was likely to succeed on the merits precisely because Fagron violated the FDCA's compounding requirements. *See* Supp. App. 62-65a.

The district court (Snyder, J., C.D. Cal.) agreed with Hope, and granted the requested preliminary injunction in July 2020. In so ruling, the court specifically held that Hope was likely to prevail on the merits because Fagron likely violated the FDCA's compounding requirements. *See* App. 80-101. Indeed, because it was undisputed that Fagron's compounds had not been approved by either federal or state regulators, the whole dispute turned on Fagron's compliance with the FDCA's compounding requirements.

In granting Hope a preliminary injunction, the district court rejected Fagron's argument that claims predicated on alleged violations of the FDCA's compounding requirements amounted to unauthorized private enforcement of the statute. *See* App. 101-05. Relying on the Federal Circuit's decision in *Allergan, Inc. v. Athena Cosm., Inc.*, 738 F.3d 1350 (Fed. Cir. 2013), which purported to apply Ninth Circuit law, and the California Supreme Court's decision in *Farm Raised Salmon Cases*, 175 P.3d 1170 (Cal. 2008), the court held that "it appears that the FDCA does not preempt state-law, consumer

protection claims based on alleged violations of the FDCA where there is a parallel state law that renders the same noncompliant conduct independently unlawful." App. 104. The court, however, failed to identify any "parallel state law" that rendered the compounding practices at issue here "independently" unlawful. *Id*. Rather, as noted above, the court concluded that Hope was likely to succeed on its claims because the challenged compounding likely violated *the FDCA's compounding provisions, Sections 503A and 503B*. *See* App. 80-101.

Because Hope disclaimed any interest in monetary relief, and thus its right to a jury trial, the district court thereafter conducted a bench trial to adjudicate the claims on the merits. Once again, the proceeding focused on whether Fagron violated the compounding requirements of FDCA Sections 503A and 503B. The district court thereafter issued Findings of Fact and Conclusions of Law, and decided that Fagron had indeed violated those FDCA provisions. *See* App. 4-68. That decision includes, among other things, "Facts Relevant to Defendants' Violation of 503A," App. 24, "Facts Relevant to Defendants' Violation of 503B 'Bulks List,'" App. 25, "Facts Relevant to Defendants' Violation of 503B 'Essentially a Copy' Provision," App. 26, "Conclusions of Law Related to Section 503A," App. 31, "Conclusions of Law Related to Section 503B 'Essentially a Copy' Provision," App. 34, and "Conclusions of Law Related to 503B 'Bulks List," App. 37. The court introduced its Conclusions of Law by declaring that "Hope has met its burden of proof with respect to its claim that defendants' distribution and sale of sodium thiosulfate drugs *violated the FDCA* and did not come within the exceptions provided by Sections 503A or 503B, and

that defendants have not established any valid defenses." App. 31 (emphasis added). And the court ultimately concluded that "defendants *violated the FDCA* because their compounding and sale of their sodium thiosulfate drug were not made pursuant to an approved application or an exception to such approval." App. 39 (emphasis added); *see also* App. 41 (same); App. 42 (same); App. 44 (same); App. 46 (same). But for Hope's disclaimer of its damages claims, a jury would have made the decision whether Fagron violated the FDCA.

Based on its conclusion that Fagron violated the FDCA, the district court further held that Fagron's challenged compounds were not exempt from ordinary drug-approval requirements, and thus violated the named States' drug-approval laws, which in turn violated the named States' consumer-protection laws. App. 38-39 (California); App. 45-46 (Connecticut); App. 40-41 (Florida); App. 43-44 (South Carolina); App. 42 (Tennessee). Accordingly, the district court directed the entry of judgment in Hope's favor, granted Hope declaratory relief, and (with certain limited exceptions) permanently enjoined Fagron from selling "any compounded sodium thiosulfate product from a 503B facility into California, Connecticut, Florida, South Carolina, or Tennessee." App. 67. The court entered a final judgment on January 18, 2022. Supp. App. 76-79a.

Just nine days later, on January 27, 2022, the FDA decided that there was no clinical need for compounding sodium thiosulfate, and thus removed that substance from the "Bulks List" of substances approved for bulk compounding. *See* 87 Fed. Reg. 4240, 4249-50 (Jan. 27, 2022). That decision—wholly

apart from the injunction in this case—effectively barred Fagron from manufacturing and distributing sodium thiosulfate compounds not only in the five States covered by the injunction, but across the entire country. Notwithstanding the FDA's decision, the district court reaffirmed and amended its permanent injunction prohibiting Fagron from distributing sodium thiosulfate compounds in the five States at issue here. Supp. App. 80-81a. The district court thereafter entered an amended final judgment, Supp. App. 82-85a, and Fagron appealed.

The Ninth Circuit reversed. In an unpublished memorandum disposition, the court held that this case is controlled by *Nexus*, which had been decided while this case was on appeal. App. 1-3. In *Nexus*, the Ninth Circuit held that the FDCA's prohibition on private enforcement preempts a private party's attempt to enforce the FDCA's compounding requirements under the rubric of a state-law unfair competition lawsuit. *See* 48 F.4th at 1049-50. In light of *Nexus*, the Ninth Circuit panel below had little difficulty concluding that Hope's claims were preempted. App. 3. "Because Hope seeks to 'enforce its interpretation' of the FDCA's rules for manufacturing compounded drugs against a competitor, the FDCA's prohibition on private enforcement and the doctrine of implied preemption bar the suit." *Id.* (quoting *Nexus*, 48 F.4th at 1050-51).

The Ninth Circuit subsequently denied Hope's petition for rehearing en banc. App. 130. Hope now seeks this Court's review.

REASONS FOR DENYING THE PETITION

This case does not warrant this Court's review because the Ninth Circuit's decision is correct and does not conflict with the decision of any other federal court of appeals or state court of last resort. *See* S. Ct. R. 10. In addition, this case presents a poor vehicle for addressing the question presented. Each point is addressed below.

I. The Ninth Circuit's Decision Is Correct And Does Not Conflict With The Decision Of Any Other Federal Court Of Appeals Or State Court Of Last Resort.

This case involves a straightforward matter of statutory interpretation. *Only* the United States may sue to restrain alleged FDCA violations (subject to a limited exception not applicable here). *See* 21 U.S.C. § 337(a). But that is exactly what petitioner Hope, a private party, has attempted to do. As the district court (which ruled in Hope's favor) recognized, Hope's ostensible state-law claims are "predicated on" alleged violations of the FDCA's compounding requirements. App. 80, 101. Hope's theory is that Fagron violated state drug-approval laws, and hence state unfair-competition laws, *because it violated the FDCA's compounding requirements*. Even a cursory review of the record in this case shows that Hope never attempted to prove its claims without attempting to prove that Fagron violated those federal requirements. *See*, *e.g.*, Supp. App. 12-23a, 62-65a.

It follows, as the Ninth Circuit held, that Hope's ostensible state-law claims are preempted by the FDCA. *See* App. 2-3; *Nexus*, 48 F.4th at 1049-50. To allow a private party to pursue a claim predicated on an alleged FDCA violation "would, in effect, permit

[the private party] to assume enforcement power which the statute does not allow and require the finder of fact to make a decision that the FDA itself did not make." *Nexus*, 48 F.4th at 1049 (internal quotation omitted). Accordingly, such a claim "is barred by the exclusive enforcement statute." *Id.*; *see also* App. 3 ("[T]he FDCA's prohibition on private enforcement bars a drug manufacturer from suing another drug manufacturer for economic harm '*because the defendant violated the FDCA*.'") (quoting *Nexus*, 48 F.4th at 1050; emphasis added).

It is no answer for Hope to argue that "§ 337(a) is not a preemption provision," and "does not say anything about States' authority to enact or enforce their own laws." Pet. 9. By its plain terms, Section 337(a) prohibits private parties from enforcing the FDCA. Insofar as state law is interpreted as a vehicle to allow private parties to enforce the FDCA, then such state law conflicts with Section 337(a) and is preempted.

Hope thus misses the point by insisting that "Section 337(a) … does not prohibit States from enacting their own laws that *borrow or parallel* the FDCA's requirements as a matter of state law." Pet. 10 (emphasis added). Here, Hope did not seek to establish that Fagron violated any state compounding requirements that "borrow" or "parallel" the FDCA's compounding requirements. Indeed, Hope did not even *identify* any state compounding requirements that "borrow" or "parallel" the FDCA's compounding requirements. Rather, Hope sought to establish that Fagron violated the FDCA's compounding requirements themselves. *See* Supp. App. 12-23a, 62-65a. The district court thus conducted a bench trial

on whether Fagron violated the FDCA's compounding requirements, not any parallel state requirements, and ultimately ruled in Hope's favor on the merits after concluding that Fagron had indeed violated the FDCA's compounding requirements, not any parallel state requirements. App. 10-38.

But of course Section 337(a) prohibits private parties from litigating such alleged FDCA violations. That provision thus barred Hope from bringing these ostensible state-law claims predicated on alleged FDCA violations, and barred the district court from adjudicating such alleged violations. But for the fact that Hope expressly disavowed any monetary relief in this case, and chose to pursue only equitable relief, a jury would have been in the anomalous position of determining whether Fagron violated the FDCA's compounding requirements before the FDA itself made any such determination. That is exactly why Section 337(a) prevents private parties from asking judges and/or juries to adjudicate alleged FDCA violations, and vests the FDA with exclusive authority to enforce the FDCA's drug provisions, including the compounding requirements.

It is thus disingenuous at best for Hope now to pretend that any violations of the FDCA's compounding requirements are entirely ancillary to its claims. In particular, Hope argues that it was required to prove only that Fagron was selling an unapproved drug to prevail on its state-law claims. *See* Pet. 12-13. But it is undisputed that Fagron's compounds were not approved drugs; indeed, by definition, compounds are not approved drugs. *See, e.g.*, *Nexus*, 48 F.4th at 1042. If simply showing that a particular drug product was unapproved were

sufficient to establish a violation of state unfair-competition laws, then *all* drug compounds would violate those laws, even though the FDCA specifically authorizes drug compounding. *See* 21 U.S.C. §§ 353a(a), 353b(a). Indeed, Hope itself acknowledges that "[t]he FDCA contains an *exception* from [its] premarket approval requirement for lawfully 'compounded' drugs." Pet. 5 (emphasis added); *see also id.* at 6 ("Sections 503A and 503B impose requirements for different kinds of compounding that, when satisfied, exempt a drug from premarket approval.").

That is why Hope litigated this case on the theory not only that Fagron's products were unapproved, but also that those products required approval in the first place—which, if they qualified as lawful compounds, they did not. And that is presumably why Hope alleged in its complaint that Fagron's drug products did *not* qualify as lawful compounds. *See* Supp. App. 12-23a.

Hope thus errs by seeking to frame the compounding issue as a "defense" that it merely sought to "head off" in its complaint. Pet. 13. Hope could not have stated a plausible claim for relief if Fagron's challenged compounds qualified as lawful compounds under the FDCA. *See, e.g.*, *Zyla Life Scis., LLC v. Wells Pharma of Houston, LLC*, No. 4:22-CV-04400, 2023 WL 6301651, at *3-4 (S.D. Tex. Sept. 27, 2023), *appeal pending*, 5th Cir. No. 23-20533; *see generally Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). That is why, as the district court below correctly observed, Hope's claims are "predicated on" Fagron's alleged violations of the FDCA's

compounding requirements, App. 80, 101, and why that court ultimately concluded that "Hope has met its burden of proof with respect to its claim that defendants' distribution and sale of sodium thiosulfate drugs *violated the FDCA* and did not come within the exceptions provided by Sections 503A or 503B, and that defendants have not established any valid defenses," App. 31 (emphasis added).

At bottom, thus, this is a case about compounding, not about drug approval. And that is precisely why the FDCA looms so large here. Although Hope asserts that "until the early 1990s FDA generally left regulation of compounding to the States," and "compounding continues to be actively regulated by the States," Pet. 5, 8 (internal quotation omitted), Hope did not base its claims on the alleged violation of any state compounding requirements. Indeed, as noted above, Hope never identified any relevant state compounding requirements. Rather, *Hope's claims are expressly based on alleged violations of the FDCA's compounding requirements. See* Supp. App. 12-23a. Not surprisingly, the district court's decision in Hope's favor, *see* App. 10-38, reads like an FDA warning letter. Having chosen to pursue claims "predicated on" alleged violations of the FDCA's compounding requirements, App. 80, 101, Hope cannot now assert that its claims are predicated on some unidentified "parallel" state compounding requirements.

It follows from the above that Hope proves nothing by invoking the States' historic "power to regulate drug sales within their borders." Pet. i; *see also id.* at 2. States are free to regulate drug sales within their borders except to the extent such regulation conflicts with federal law. And that means that States cannot

create a private cause of action under state law predicated on a violation of a federal law insofar as federal law prohibits such private enforcement. A State, in other words, cannot give a private party like Hope a private right of action to enforce federal law that federal law itself expressly withholds. The States' historic police powers do not extend to providing remedies for violations of federal law. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001).

It is thus pure hyperbole for Hope to assert that "[t]he 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." Pet. 1-2. No one disputes that States have that power. What a State cannot do, as the Ninth Circuit recognized, is create a private right of action to enforce a federal statute where Congress has expressly precluded private enforcement of that federal statute. *See* App. 2-3; *Nexus*, 48 F.4th at 1049-50. The FDA, not judges and juries across the country, is entitled to decide in the first instance whether the FDCA's compounding requirements have been violated.

Precisely because Hope's claims are predicated on alleged violations of the FDCA, not any parallel state laws, Hope errs by arguing that the decision below "conflicts with the decisions of other federal courts of appeals and the California Supreme Court," as well as "with the United States' own views on FDCA preemption." Pet. 18.

Hope begins by invoking the Federal Circuit's decision in *Allergan*. *See* Pet. 19-20. The plaintiff there alleged that the defendant violated California

law by selling an unapproved drug to stimulate eyelash growth. The central dispute was whether the product was a drug (which required approval) or a cosmetic (which did not). Purporting to apply Ninth Circuit law, *see* 738 F.3d at 1354, the Federal Circuit held that the claim was not preempted because it was not predicated on an alleged violation of federal law, *see id.* at 1355-56. Rather, the court held, the question whether the product was a drug arose under California's Sherman Law, which defines "drugs." Cal. Health & Saf. Code § 109925(a). The fact that state law on this issue may "parallel" federal law, or "incorporate[]" federal regulations, in the Federal Circuit's view, was insufficient to trigger preemption. 738 F.3d at 1354-56. Because the plaintiff's state-law claim there, unlike here, was not predicated on an alleged violation of the FDCA, as opposed to a parallel provision of state law, the court had no occasion to address whether such a claim would be preempted.*

---

* In *Nexus*, the Ninth Circuit opined in *dicta* that *Allergan* was wrong as a matter of Ninth Circuit law. *See* 48 F.4th at 1049-50. That point alone, of course, refutes Hope's allegation of a "circuit split" between the Federal and Ninth Circuits, as the Federal Circuit was merely purporting to apply Ninth Circuit law. Pet. 19-20. Needless to say, the Ninth Circuit itself is the ultimate arbiter of Ninth Circuit law. For the reasons explained in the text, however, the Ninth Circuit did not need to disavow *Allergan* in order to hold the claim in *Nexus* preempted, because the plaintiff in *Allergan* (unlike Hope or the plaintiff in *Nexus*) predicated its claims on alleged violations of

Hope next argues that the decision below "conflicts with the California Supreme Court's decision in *Farm Raised Salmon*." Pet. 20. Again, Hope is wrong. The plaintiff there alleged that the defendants violated California law by selling artificially colored salmon without disclosing the use of color additives. 175 P.3d at 1177-84. California's Sherman Law specifically addresses this issue. *See* Cal. Health & Saf. Code § 110740 ("Any food is misbranded if it bears or contains any … artificial coloring … unless its labeling states that fact."). Additionally, the Sherman Law incorporates "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the [FDCA]" as "the food labeling regulations of this state." Cal. Health & Saf. Code § 110100(a). And a specific provision of federal law specifies that "no State … may directly or indirectly establish … any requirement for the labeling of food … that is not identical to the requirement [of federal law]." 21 U.S.C. § 343-1(a).

Under these circumstances, the California Supreme Court had little trouble concluding that the plaintiffs' state-law claims escaped preemption. *See* 175 P.3d at 1177-84. Indeed, as noted above, the relevant federal food-labeling law (which has no application here) made it clear that States *could* impose food labeling requirements identical to federal requirements. *See id.* at 1175, 1178-81. Nor was the FDCA's ban on private enforcement implicated in that case, because the plaintiffs' claims there (unlike Hope's claims here) were not predicated on a violation of the FDCA, as

---

state laws that paralleled the FDCA, not alleged violations of the FDCA itself.

opposed to parallel provisions of state law. *See id.* at 1181-82. "That the Sherman Law imposes obligations identical to those imposed by the FDCA, as it must under section 343-1, does not substantively transform plaintiffs' action into one seeking to enforce federal law." *Id.* at 1181.

Hope's reliance on a trio of Fifth Circuit cases is misplaced for the same reason. *See* Pet. 10, 22 (citing *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 v. Bos. Sci. Corp.*, 631 F.3d 762, 774-75 (5th Cir. 2011)). Those cases stand only for the unremarkable proposition that the FDCA does not preempt the application of state laws that "parallel" the FDCA. *Spano*, 65 F.4th at 264; *Bass*, 669 F.3d at 514; *Hughes*, 631 F.3d at 775; *see generally Zyla Life Scis.*, 2023 WL 6301651, at *5. Those cases say nothing about ostensible state-law claims, like the ones at issue here, predicated on alleged violations of the FDCA itself, as opposed to a parallel provision of state law.

Even more farfetched is Hope's passing allegation of a "split" between the Ninth Circuit's decision in this case and the First Circuit's decision in *Azurity Pharms., Inc. v. Edge Pharma, LLC*, 45 F.4th 479 (1st Cir. 2022). Pet. 23-24. As a threshold matter, that case did not involve federal preemption of state law at all, but the relationship between two federal statutes, the FDCA and the Lanham Act, 15 U.S.C. § 1051 *et seq*. *See id.* at 499-502; *see generally POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 117-18 (2014) (distinguishing between federal preemption of state law and reconciliation of federal statutes).

The plaintiff in *Azurity* alleged that the defendant violated the Lanham Act by stating on its website that its products complied with the FDCA's compounding requirements. *See id.* at 483. The First Circuit acknowledged that, under some circumstances, a Lanham Act claim involving statements regarding FDCA compliance might impermissibly intrude on the FDA's primary jurisdiction, *see id.* at 500-01 (citing *Amarin Pharma, Inc. v. ITC*, 923 F.3d 959, 968 (Fed. Cir. 2019), but held that "the adjudication of th[e] claim [in *Azurity*] simply requires a court to ascertain whether a particular drug appears on either the list of 'bulk drug substances for which there is a clinical need,' or on the drug shortage list," *id.* at 501 (quoting 21 U.S.C. § 353b(a)(2)(A)). Under these specific facts, the First Circuit "perceive[d] no basis for finding the kind of conflict between Lanham Act enforcement and FDA policy discretion that [the defendant] contends could supply the basis for finding a Lanham Act claim to be precluded by the FDCA." *Id.* at 502. That decision has no bearing on the question presented here, "[w]hether 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." Pet. i.

Just as the Ninth Circuit's decision below comports with the decisions of other courts, the Ninth Circuit's decision below comports with the invitation briefs filed in this Court by the Solicitor General in *Allergan* and *Farm Raised Salmon*. *See* U.S. Br. as Amicus Curiae*, Athena Cosmetics, Inc. v. Allergan, Inc.*, 576 U.S. 1054 (2015) (No. 13-1379), 2015 WL 2457643; U.S. Br. as Amicus Curiae, *Albertson's, Inc. v. Kanter*, 555 U.S. 1097 (2009) (No. 07-1327), 2008 WL 515069. By Hope's own admission, those briefs stand for the

proposition that "the parallel nature of … state laws … [does] not justify disregarding those state laws and treating the action as one improperly brought under the FDCA." Pet. 21; *see also id.* at 20. "'Actions to enforce state laws that impose requirements identical to those under the FDCA are not actions to enforce the FDCA itself.'" *Id.* at 21 (quoting U.S. *Albertson's* Br. 12). The problem for Hope, as noted above, is that its claims are *not* predicated on the violation of any state compounding requirements identical or parallel to the FDCA's compounding requirements; rather, its claims are predicated on the violation of the FDCA's compounding requirements themselves. *See* Supp. App. 12-23a.

Hope, in short, is trying to conjure up confusion out of clarity. It is trying to conflate two distinct lines of cases: (1) those in which the plaintiff's claims are predicated on state law that incorporates or parallels federal law, and (2) those in which the plaintiff's claims are predicated on federal law without any corresponding state law that incorporates or parallels federal law. This case, like *Nexus*, falls into the latter category. The cases on which Hope relies fall into the former category. Accordingly, because the Ninth Circuit correctly resolved this case, and the decision below does not implicate any circuit conflict, this Court's review is unwarranted.

II. This Case Is A Poor Vehicle To Address The Question Presented.

And this Court's review is unwarranted wholly apart from the merits and the absence of a circuit split for the simple reason that this case is a poor vehicle to address the question presented. The case is limited to declaratory and injunctive relief barring Fagron from

distributing its sodium thiosulfate compounds in five States. *See* App. 67-68; Supp. App. 80-85a. But shortly after the entry of that judgment, the FDA effectively barred Fagron from distributing its sodium thiosulfate compounds anywhere in the Nation by removing sodium thiosulfate from the "Bulks List" approved for compounding under FDCA Section 503B. Accordingly, there is no reason to continue fighting about whether the district court was right to grant declaratory and injunctive relief. In light of the FDA's decision, it is no longer lawful for Fagron to compound sodium thiosulfate, and Fagron has acknowledged that it will not do so. Thus, Hope cannot obtain any further relief from this lawsuit, and review by this Court would not change anything.

Ironically, Hope tries to use this development to its advantage, arguing that the FDA's decision shows that there is no conflict between federal and state law here. *See* Pet. i, 14. What the FDA's decision really shows is that Hope was seeking relief in the wrong forum by purporting to sue under state law to try to block Fagron's compounding. It is the FDA, not judges or juries in private lawsuits around the country, that Congress has entrusted with determining whether particular compounding practices are lawful under Section 503A and 503B of the FDCA. The fact that the district court in this case held a trial to determine whether Fagron's practices violated those FDCA provisions, *see* App. 10-38, only underscores how far this case went off the rails in the district court.

What Hope is really seeking now, in short, is an advisory opinion on FDCA preemption in compounding cases. Fagron's acknowledgment that, in light of the FDA's decision, "it cannot lawfully sell

its drug under the FDCA," Pet. 35, *see also id.* at 14, only underscores that this lawsuit is now pointless. Needless to say, this Court is not in the business of resolving academic questions without real-world consequences. *See* U.S. Const. art. III. At the very least, wholly apart from the merits, this case would require extensive briefing on mootness if the Court were to grant review; were the Court to grant review, the case would have "dismissed as improvidently granted" stamped all over it.

CONCLUSION

For the foregoing reasons, the Court should deny the petition for writ of certiorari.

Respectfully submitted,

KEITH J. WESLEY
ELLIS GEORGE LLP
2121 Avenue of the Stars
Suite 3000
Los Angeles, CA 90067
(310) 274-7100

April 12, 2024

CHRISTOPHER LANDAU
Counsel of Record
ELLIS GEORGE LLP
1155 F Street N.W.
Suite 750
Washington, DC 20004
(202) 249-6900
clandau@ellisgeorge.com