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

APPLICATION TO JUSTICE ELENA KAGAN FOR AN EXTENSION OF TIME TO FILE A PETITION FOR WRIT OF CERTIORARI

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TO: THE HONORABLE ELENA KAGAN, ASSOCIATE JUSTICE OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE NINTH CIRCUIT

Pursuant to Supreme Court Rule 13.5, Petitioner Hope Medical Enterprises, Inc. respectfully requests a 14-day extension of the time to file a petition for a writ of certiorari up to and including January 16, 2024. The United States Court of Appeals for the Ninth Circuit issued its decision on July 26, 2023, *see* Attachment A, and denied rehearing en banc on October 2, 2023, *see* Attachment B. Absent an extension, a petition for certiorari would be due on January 2, 2024. This application is timely because it has been filed more than ten days before the date on which the petition is otherwise due. S. Ct. R. 13.5. This Court has jurisdiction under 28 U.S.C. § 1254(1).

1. This case implicates States' historical 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, that power belonged exclusively to the States. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). Not until 1938 did Congress enact a "provision for premarket approval of new drugs" as part of the Food, Drug, and Cosmetic Act. *Id.* The FDCA "supplemented" but did not override the "protection for consumers already provided by state regulation and common-law liability." *Id.* While expanding FDA's authority, Congress still "took care to preserve state law." *Id.* at 567. Thus, while the FDCA contains a standing provision stating 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 standing provision has long been understood not to prohibit States from enacting laws that borrow or "parallel" the FDCA's requirements as a matter of state law. *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354–

56 (Fed. Cir. 2013), *cert. denied*, 576 U.S. 1054 (2015); *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).

2. The Ninth Circuit held otherwise in *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (9th Cir. 2022). In *Nexus* the Ninth Circuit held that FDCA § 337(a) preempts state statutes that prohibit the in-state sale of drugs that have not received premarket approval from the U.S. Food and Drug Administration or appropriate state agencies, even if those state statutes impose the exact same requirements as the FDCA. *Id.* at 1046–50. 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 prohibited by § 337(a). *Id.*; *see id.* at 1049–50 (holding 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'"). The Ninth Circuit also 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. In the decision below, the Ninth Circuit applied *Nexus* to hold that the FDCA preempted Petitioner's state-law claims against Respondents. *Hope Med.*

Enters., Inc. v. Fagron Compounding Servs., LLC, 2023 WL 4758454 (9th Cir. July 26, 2023). Petitioner manufactures and sells "Sodium Thiosulfate Injection," an FDA-approved drug. *Hope Med. Enters. Inc. v. Fagron Compounding Servs., LLC*, 2021 WL 4963516, at *1, *12 (C.D. Cal. Oct. 26, 2021). Respondents sell a competing sodium thiosulfate drug that has not received premarket approval from FDA or any state agency. *Id.* Petitioner sued Respondents under five States' unfair-competition laws, claiming that Respondents' sales of their drug violated the five States' laws prohibiting the sale of unapproved drugs. *See id.* at *14–18. Although Respondents argued that their drug was exempt from premarket approval under the FDCA because it was "compounded," the district court found after trial that Respondents' drug was *not* exempt from premarket approval because Respondents did not comply with the FDCA's compounding exception. *Id.* at *12–14. Indeed, Respondents have now conceded that the FDCA prohibits them from selling their drug without premarket approval. *See* CA9 Excerpts of Record at 1-ER-39; CA9 Opening Br. at 19, 31; CA9 Opp. to Mot. to Stay Mandate at 8. Therefore, it is undisputed that state law and the FDCA equally prohibit Respondents from selling their unapproved drug. The Ninth Circuit nonetheless held that "*Nexus* controls here" and that, under *Nexus*, "the FDCA's prohibition on private enforcement and the doctrine of implied preemption bar the suit." *Hope*, 2023 WL 4758454, at *1.

4. Petitioner intends to file a petition for a writ of certiorari. The Ninth Circuit's decisions in this case and *Nexus*, which hold that FDCA § 337(a) preempts state statutes imposing the exact same drug-approval requirements as the FDCA,

conflict with this Court's decisions in *Wyeth* and *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 117 (2014); openly create a circuit split with the Federal Circuit's decision in *Athena*, 738 F.3d at 1355–56, which held the FDCA does not preempt the California drug-approval statute at issue in this case, *see Nexus*, 48 F.4th at 1049–50 (acknowledging split with *Athena*); and conflict with the California Supreme Court's decision in *Farm Raised Salmon*, 175 P.3d at 1181–84, which likewise held the FDCA does not preempt a California statute that paralleled the FDCA. The Ninth Circuit's decisions also conflict with the United States' own position that the FDCA does not preempt state drug-approval statutes, which it presented to this Court in invitation briefs in *Athena* and *Farm Raised Salmon*. *See* U.S. Br. as Amicus Curiae, *Athena*, 576 U.S. 1054 (No. 13-1379), 2015 WL 2457643; U.S. Br. as Amicus Curiae, *Albertson's*, 555 U.S. 1097 (No. 07-1327), 2008 WL 5151069. This issue is immensely important because the Ninth Circuit's outlier approach to FDCA preemption eviscerates the States' historical power to regulate the in-state sale of drugs, *see Wyeth*, 555 U.S. at 566, and essentially converts § 337(a) into a *field preemption* provision ousting the States from the entire field of health and safety regulation.

5. The Ninth Circuit has stayed its mandate pending the resolution of Petitioner's petition for certiorari. CA9 Dkt. 79.

6. Petitioner respectfully requests an extension of 14 days, to and including January 16, 2024, to prepare a petition for certiorari. An extension is necessary because the current deadline of January 2, 2024 conflicts with undersigned counsel's prescheduled plans for the December and New Year holidays. A 14-day extension

would give undersigned counsel sufficient time to prepare and file a petition for certiorari and would not cause material delay, as this Court could still hear the case during the upcoming Term.

7. Counsel for Respondents has stated that Respondents consent to the requested 14-day extension.

CONCLUSION

For the foregoing reasons, this Court should grant the requested extension of time for Petitioner's petition for certiorari.

Respectfully submitted,

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