No. 25-257

In the Supreme Court of the United States

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

v.

ZYLA LIFE SCIENCES, L.L.C.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, impliedly preempts private state-law suits to enjoin the in-state sale of a drug that has not been approved by the Food and Drug Administration.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Constitution, statutes, and regulations:

Miscellaneous—Continued: Page

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INTEREST OF THE UNITED STATES

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

INTRODUCTION

The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, regulates drug manufacturing, marketing, and distribution. Under the FDCA, drug manufacturers must receive approval from the Food and Drug Administration (FDA) before new drugs may be marketed. 21 U.S.C. 355(a). While assigning FDA an important role in protecting health and safety, "Congress took care to preserve state law." *Wyeth* v. *Levine*, 555 U.S. 555, 567 (2009).

Consistent with that understanding, the court below correctly held that the FDCA does not impliedly preempt

state-law claims that challenge the in-state sale of drugs that FDA has not approved. Pet. App. 9a-11a. That holding follows from this Court's precedents addressing parallel state and federal laws, and it accords with the FDCA's medical-device provisions, which allow enforcement of state-law requirements that are identical to federal rules, while expressly preempting other forms of state regulation.

In the view of the United States, this Court's review is not warranted. Although the court of appeals' decision conflicts with a Ninth Circuit decision, there is some confusion on the issue within the Ninth Circuit itself. Moreover, this case would not be a suitable vehicle in which to consider the question presented because FDA is currently considering whether to take regulatory action with respect to the drug at issue here. If the Court granted review, FDA might reach a decision on that regulatory action while the Court was considering this case on the merits, and the agency's decision could materially affect this Court's analysis. The petition for a writ of certiorari should be denied.

STATEMENT

A. Legal Background

Under the FDCA, "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug" unless FDA has approved an application "with respect to such drug." 21 U.S.C. 355(a). While the FDCA has long required premarket approval of new drugs, "[f]or approximately the first 50 years after the enactment of the FDCA, the FDA generally left regulation of [drug] compounding to the States." *Thompson* v. *Western States Med. Ctr.*, 535 U.S. 357, 362 (2002). Traditional compounding "is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create

a medication tailored to the needs of an individual patient." *Id.* at 360-361. For example, a particular patient may be "allergic to an ingredient in a mass-produced product." *Ibid.* A compounder may accommodate the patient by preparing a version of the drug that does not contain the allergen.

Over time, FDA became concerned "that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Thompson*, 535 U.S. at 362. In response to those concerns and a multi-state outbreak of fungal meningitis caused by compounded drugs in 2012, Congress amended the FDCA to address compounding. As amended, the FDCA permits drug compounding without premarket approval in two circumstances. First, licensed pharmacists and physicians may compound drugs for identifiable individual patients with a prescription, subject to various restrictions. 21 U.S.C. 353a. Second, registered "[o]utsourcing facilities" may compound drugs at scale and without a patient-specific prescription, so long as the facilities satisfy 11 statutory criteria. 21 U.S.C. 353b(a)(1)-(11). As relevant here, outsourcing facilities may not compound using bulk drug substances (also known as active pharmaceutical ingredients, see 21 C.F.R. 207.3) unless (i) a particular bulk drug substance "appears on a list established by the Secretary [of Health and Human Services] identifying bulk drug substances for which there is a clinical need," or (ii) the drug being compounded from the bulk drug substance "appears on the [FDA] drug shortage list." 21 U.S.C. 353b(a)(2)(A)(i) and (ii).

The FDCA does not create a private right of action. With one exception not relevant here, 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).

B. The Present Controversy

1. This case involves the sale of indomethacin suppositories. Pet. App. 7a-8a. Indomethacin is used to treat rheumatoid arthritis and other ailments. *Id.* at 7a. Indomethacin does not currently appear on FDA's list of bulk drug substances for which the agency has found a clinical need for compounding using bulks (known as the 503B bulks list). See FDA, *503B Bulk Drug Substances List* (updated Aug. 21, 2023), https://www.fda.gov/drugs/human-drug-compounding/503b-bulk-drug-substances-list; see 21 U.S.C. 353b(a)(2)(A)(i). Nor do indomethacin suppositories appear on FDA's drug shortage list. FDA, *FDA Drug Shortages: Current and Resolved Drug Shortages and Discontinuations Reported to FDA*, https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; see 21 U.S.C. 353b(a)(2)(A)(ii).

Indomethacin has been nominated, however, to appear on the 503B bulks list. While FDA evaluates nominated bulk drug substances for inclusion on the list, it has sorted the nominated substances into three categories. FDA, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act* 6 (Jan. 2025), https://www.fda.gov/media/94402/download (*Interim Policy*). Category 1 substances are those that "may be eligible for inclusion on the 503B bulks list, were nominated with sufficient supporting information for FDA to evaluate them, and do not appear on any other list." *Ibid.* Category 2 substances were likewise "nominated with sufficient supporting information to permit FDA to evaluate them," but "FDA has identified significant safety risks related to the use of the[ ] substances in compound-

ing." *Ibid.* Category 3 substances are those that "were nominated with insufficient supporting information for FDA to evaluate them," and they "can be renominated with sufficient supporting information." *Ibid.*

FDA has placed indomethacin in Category 1. FDA, *Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act* 5 (Mar. 21, 2025) https://www.fda.gov/media/94164/download. FDA's guidance states that "[a]t this time, FDA does not intend to take action against an outsourcing facility for compounding a drug product using a bulk drug substance" in Category 1, if certain conditions are met. *Interim Policy* 11; see *id.* at 11-12. That guidance applies until the agency either makes a final decision regarding the drug's potential placement on the 503B bulks list or removes it from Category 1. *Id.* at 7. FDA's guidance "does not establish any rights for any person and is not binding on FDA or the public." *Id.* at 1.

2. Respondent is a pharmaceutical company that obtained premarket approval from FDA to market suppositories containing indomethacin. Pet. App. 7a-8a. Petitioner is a registered outsourcing facility that sells compounded indomethacin suppositories without premarket approval from FDA. *Id.* at 8a. Both parties sell their products throughout the United States. *Id.* at 7a, 55a.

Respondent sued petitioner in the United States District Court for the Southern District of Texas, seeking to enjoin petitioner from manufacturing and selling its indomethacin suppositories in California, Colorado, Connecticut, Florida, South Carolina, and Tennessee. Pet. App. 55a-56a. Respondent alleged that petitioner's sale of the suppositories in those six States violates unfair-competition statutes that require premarket approval

from FDA before drugs may be sold in those States. *Id.* at 56a. See Cal. Health & Safety Code § 111550(a); Colo. Rev. Stat. § 12-280-131(1); Conn. Gen. Stat. § 21a-110; Fla. Stat. § 499.023; S.C. Code § 39-23-70(a); Tenn. Code § 53-1-110(a). Petitioner moved to dismiss respondent's complaint, arguing that the FDCA preempts the state-law claims. Pet. App. 57a.

The district court granted petitioner's motion to dismiss. Pet. App. 53a-65a. The court concluded that "[w]hile most prescription drugs require premarket approval, the FDCA excepts qualifying compounding outsourcing facilities from this requirement." *Id.* at 62a. Based on that understanding, the court viewed respondent's "assertion that [petitioner] must obtain premarket approval" in order for the sales to comply with state law as "add[ing] to the federal requirements under the FDCA" and imposing requirements "'beyond' those imposed by the FDA." *Id.* at 62a-63a (citation omitted). The court therefore held that respondent's claims are impliedly preempted. *Id.* at 64a. The court also denied respondent's request to amend its complaint to allege that petitioner had failed to meet the FDCA's requirements for compounding by registered outsourcing facilities. *Id.* at 64a-65a. The court concluded that respondent's claims would be preempted regardless of any noncompliance with those requirements because the United States has exclusive statutory authority to enforce the FDCA's premarket-approval requirement. *Ibid.*

3. The court of appeals reversed. Pet. App. 26a-50a. The court subsequently denied a petition for rehearing en banc, *id.* at 66a, and revised its opinion, *id.* at 1a-25a. This brief cites and discusses the revised opinion.

The court of appeals explained that, under this Court's precedents, "when state law mirrors federal law," it

complies with the Supremacy Clause and is not preempted. Pet. App. 10a (citing *Asbell* v. *Kansas*, 209 U.S. 251, 258 (1908)). The court of appeals concluded that, because the state laws respondent had invoked "make[ ] federal law [their] own, * * * there can be 'no conflict in terms' and no preemption." *Id.* at 11a (quoting *California* v. *Zook*, 336 U.S. 725, 735 (1949)) (brackets in original).

The court of appeals rejected petitioner's argument that permitting parallel enforcement under state law would encroach on federal officials' enforcement discretion under the FDCA. Pet. App. 15a-20a. The court explained that the logic of that position is contrary to this Court's decision in *Wyeth* v. *Levine*, 555 U.S. 555 (2009), which held, "in the specific context of the FDCA," "that States could regulate concurrently with the Federal Government the same primary conduct related to drug safety and effectiveness in different ways without interfering with FDA oversight," Pet. App. 20a.

The court of appeals likewise rejected petitioner's reliance on *Buckman Co.* v. *Plaintiff's Legal Committee*, 531 U.S. 341 (2001), in which this Court held that state-law claims alleging fraud on the FDA were preempted. Pet. App. 20a-23a. The court of appeals explained that *Buckman* did not involve "state law mirroring federal requirements," *id.* at 22a, but instead dealt with claims of fraud against federal agencies—a theory of liability that is "inherently federal in character," *Buckman*, 531 U.S. at 347; see Pet. App. 21a. The court observed that respondent's claims do not allege wrongdoing by petitioner vis-à-vis FDA and thus do not seek to "polic[e] the uniquely federal relationship between [petitioner] and the FDA." Pet. App. 22a.

The court of appeals also rejected petitioner's contention that respondent's state-law claims would add to the FDCA's requirements and therefore must be preempted. Pet. App. 8a-9a n.2. The court explained that the state-law requirements to obtain premarket approval could be said to add to the FDCA only if those requirements would impose liability on petitioner for selling drugs that comply with all of Section 353b's conditions for exemption from premarket approval. *Ibid.* The court concluded that, because petitioner could not have established its compliance with each of those requirements at the present motion-to-dismiss stage, petitioner could not show at this stage of the case that respondent's claims are preempted under that theory. *Ibid.*

DISCUSSION

The court of appeals correctly held that, at least for purposes of petitioner's motion to dismiss, the FDCA does not impliedly preempt respondent's state-law unfair-competition claims. At this stage of the case, there is no basis for petitioner's assertion that the state-law requirements respondent seeks to enforce will add to or otherwise conflict with federal law. While petitioner has identified a Ninth Circuit decision that reached a contrary result, the conflict is shallow and uncertain, and this case would be a poor vehicle to resolve it. The petition for a writ of certiorari should be denied.

A. The Decision Below Is Correct

1. Respondent's claims rest on state laws that parallel the FDCA by prohibiting the marketing of drugs without FDA approval. Pet. App. 56a. See Cal. Health & Safety Code § 111550(a); Colo. Rev. Stat. § 12-280-131(1); Conn. Gen. Stat. § 21a-110; Fla. Stat. § 499.023;

S.C. Code § 39-23-70(a); Tenn. Code § 53-1-110(a). Unlike the FDCA, those statutes do not include an exception for certain drugs compounded by outsourcing facilities. But respondent's suit to enforce those statutes is premised on state unfair-competition laws, each of which includes—expressly or by interpretation—a safe harbor for conduct that complies with, or is permitted or authorized by, federal or state law. See *Cel-Tech Commc'ns, Inc.* v. *Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 182 (1999); *Beasley* v. *Tootsie Roll Indus., Inc.*, 85 Cal. App. 5th 901, 923 (2022); Colo. Rev. Stat. § 6-1-106; Conn. Gen. Stat. § 42-110c(a)(1); Fla. Stat. § 501.212(1); S.C. Code § 39-5-40; Tenn. Code § 47-18-111. Respondent asserts on that basis (Br. in Opp. 15-16, 23) that petitioner can be held liable under state law only if its sales of unapproved drugs violate the FDCA, and that those sales do not violate the FDCA if they fall within 21 U.S.C. 353b's exemption.

The FDCA does not preempt such parallel claims challenging the sale of drugs that FDA has not approved. This Court has recognized that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Wyeth* v. *Levine*, 555 U.S. 555, 575 (2009). To the extent that the state-law restrictions that respondent invokes incorporate the FDCA's own requirements and exemptions as interpreted by FDA, petitioner cannot plausibly argue that it is impossible to comply with both federal and state law, or that the relevant state laws impose requirements that the FDCA does not. See Pet. App. 8a-9a n.2. Nor is there any indication that allowing States to provide additional remedies for distributing drugs in violation of FDA premarket-approval requirements is

contrary to the "purposes and objectives of Congress." *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941).

To the contrary, this Court has long held in various contexts that States may impose liability for failing to obtain required federal approvals without running afoul of implied-preemption principles. In *California* v. *Zook*, 336 U.S. 725 (1949), for example, the Court held that a California law prohibiting commercial transportation arrangements on public highways unless the carrier had a permit from the federal Interstate Commerce Commission was not preempted by a "substantially" identical provision in the federal Motor Carrier Act. *Id.* at 726-727, 737. The Court explained that there was "no conflict in terms, and no possibility of such conflict," because "the state statute makes federal law its own." *Id.* at 735.

Similarly in *Asbell* v. *Kansas*, 209 U.S. 251 (1908), the Court held that a Kansas law prohibiting the transportation of cattle into the State unless the cattle had been inspected by the United States Bureau of Animal Industry did not conflict with a federal statute requiring the Bureau to inspect cattle before they were transported across state lines. *Id.* at 257-258. The Court explained that the Kansas law did not conflict with federal law, but instead "recognize[d] the supremacy of the national law and conform[ed] to it." *Id.* at 258.

The court of appeals correctly recognized that the same analysis holds here. Pet. App. 10a-11a. As in *Zook* and *Asbell*, to the extent the state laws that respondent invokes incorporate the FDCA's requirements for FDA premarket approval, those laws "make[] federal law [their] own" and therefore are not preempted. *Id.* at 11a (quoting *Zook*, 336 U.S. at 735) (brackets in original).

That conclusion is consistent with the broader FDCA framework, whereas petitioner's approach would produce incongruous results. Elsewhere in the FDCA, Congress enacted an express preemption provision for state medical-device regulation, but chose to preempt only those state-law requirements that are "different from, or in addition to," federal medical-device requirements. 21 U.S.C. 360k(a). That provision "does not prevent a State" from enacting a parallel provision that "provid[es] a damages remedy for claims premised on a violation of" federal requirements. *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 330 (2008); see *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 495 (1996); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); cf. *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005) (permitting state requirements that are "*genuinely* equivalent" to federal requirements under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*).

While Congress expressly preempted some state-law requirements for medical devices, Congress "declined to enact" an express preemption provision for prescription drugs. *Wyeth*, 555 U.S. at 567. Yet under petitioner's view that the FDCA preempts even those state drug laws that incorporate federal requirements, the FDCA would have broader preemptive effect for prescription drugs than for medical devices. That anomalous result finds no support in the FDCA or in this Court's precedents.

2. Petitioner's contrary arguments rest on flawed understandings of the FDCA's enforcement provision, this Court's decision in *Buckman Co.* v. *Plaintiff's Legal Committee*, 531 U.S. 341 (2001), and the reach of the state statutes at issue here.

a. Petitioner contends (Pet. 18-19) that allowing respondent's state-law claims to go forward is inconsistent with 21 U.S.C. 337(a), which provides that "proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." Nothing in Section 337(a)'s text suggests that it precludes actions brought under state law. As FDA recognized when it promulgated regulations to implement Section 337, the provision "applies only to proceedings to enforce the [FDCA]," and it therefore "does not prohibit a State from enforcing an identical State law." 58 Fed. Reg. 2457, 2458 (Jan. 6, 1993). By the same token, States may also authorize private suits to enforce state laws that incorporate federal requirements. Such authorization is permissible because actions to enforce state laws that mirror the FDCA are not actions to enforce the FDCA itself. See Pet. App. 24a n.8.

b. Petitioner fares no better in asserting that *Buckman* supports preemption here. Pet. 18-20. In *Buckman*, the plaintiffs alleged that they had suffered injuries from medical devices that FDA had cleared for sale. 531 U.S. at 343. The plaintiffs contended that the defendant—a consultant that had assisted the device manufacturers in navigating the federal regulatory process—had made fraudulent representations to FDA and that, but for those representations, "the FDA would not have [cleared] the devices, and plaintiffs would not have been injured." *Ibid.*; see *id.* at 346.

This Court held that the plaintiffs' fraud-on-the-FDA claim was preempted. *Buckman*, 531 U.S. at 348. The Court emphasized that the fraud claim at issue concerned "the relationship between a federal agency and the entity it regulates," a matter that is "inherently federal in character." *Id.* at 347-348 (distinguishing *Lohr*,

518 U.S. at 485). The Court explained that "the federal statutory scheme amply empowers the FDA to punish and deter fraud" against the agency, *id.* at 348, while state-law claims asserting such fraud "would exert an extraneous pull" on the relationship between FDA and those it regulates, *id.* at 353.

The Court in *Buckman* further explained that allowing plaintiffs to pursue state-law fraud-on-the-FDA claims could compromise FDA's "flexibility" to pursue "difficult (and often competing) objectives" under the FDCA's medical-device provisions. 531 U.S. at 349. Such claims would interfere with FDA's prerogative to decide for itself whether it had been defrauded and what sanctions to impose; would make the abbreviated clearance process the defendant had invoked less attractive and efficient for applicants and the agency; and could deter off-label uses of devices. *Id.* at 348-351. The Court also explained that permitting state-law fraud-on-the-FDA claims would "cause applicants to fear that their disclosures to the FDA" would "later be judged insufficient in state court." *Id.* at 351. That could lead applicants to "submit a deluge of information that [FDA] neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." *Ibid.*

Consistent with that reasoning, this Court has described *Buckman*'s holding as resulting from the "uniquely federal area[ ] of regulation" implicated by a claim of "fraud on a federal agency," *Chamber of Commerce* v. *Whiting*, 563 U.S. 582, 604 (2011), and from the "threat[ ]" of "serious disruption," *Kansas* v. *Garcia*, 589 U.S. 191, 212 (2020), that would result if fraud-on-the-FDA claims were allowed to proceed. As the court of appeals recognized, this case lacks those features. Pet. App. 20a-25a. Allowing respondent's state-law claims to

proceed would create no risk that manufacturers will avoid seeking FDA premarket approval, *Buckman*, 531 U.S. at 350, or will "submit a deluge" of unnecessary information with their applications, *id.* at 351. Respondent's state-law claims do not question the validity of any premarket-approval (or other) decision made by FDA, and respondent does not currently ask a court to evaluate the accuracy or completeness of petitioner's disclosures to any federal agency. Thus, allowing respondent's state-law claims to proceed will not compromise FDA's regulation of outsourcing facilities or "directly interfere[] with the operation of [a] federal program." *Whiting*, 563 U.S. at 604.

Petitioner emphasizes (Pet. 18) language in *Buckman* explaining that the plaintiffs' preempted fraud claims "exist[ed] solely by virtue of the FDCA disclosure requirements." *Buckman*, 531 U.S. at 353. Petitioner argues (Pet. 18) that respondent's claims likewise "rest solely on the allegation that [petitioner's] compounded indomethacin suppositories lack FDA premarket approval." Although lack of FDA approval is one element of respondent's claims, those claims (unlike the claims in *Buckman*) do not turn on petitioner's "dealings with the FDA." *Buckman*, 531 U.S. at 347. Petitioner does not claim to have submitted a marketing application to FDA, and FDA has not approved petitioner's product for marketing. Accordingly, at this juncture, petitioner has not shown that respondent's claims create a significant risk that "disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351.

Here, the viability of respondent's state-law claims depends on FDA's *actual* regulatory conduct—in par-

ticular, on the facts that FDA has not placed indomethacin on the 503B bulks list and has not placed indomethacin suppositories on the agency's drug shortage list. See p. 4, *supra*. Respondent correctly infers from those facts that Section 353b does not presently exempt petitioner's indomethacin suppositories from the FDCA's premarket-approval requirement. Respondent does not ask any court to determine what FDA *would have* done if petitioner had submitted more accurate or complete information. That Congress charged FDA with evaluating drugs for approval does not suggest an intent to prohibit States from relying on FDA's determinations to effectuate their own regulation of drug distribution within their borders.

c. Petitioner asserts (Pet. 19-20; Cert. Reply Br. 10-11) that respondent's state-law claims "add to" the FDCA's requirements and therefore conflict with federal law. That is incorrect.

Petitioner contends (Pet. 19-20; Cert. Reply Br. 10-11) that respondent's state-law claims omit the FDCA's compounding exceptions and therefore require premarket approval in circumstances where the FDCA does not. But each of the state laws at issue includes a safe harbor for conduct that complies with, or is permitted or authorized by, applicable law. See p. 9, *supra*; see Br. in Opp. 16 & n.5. Based on those safe harbors, respondent contends (Br. in Opp. 16) that the "relevant state-law requirements are identical to the FDCA's requirements."

At this stage of the case, the district court has not yet construed the safe harbors to determine whether that contention is correct. But even if the relevant state laws (including the safe harbors) are not ultimately construed to be identical to the FDCA's requirements in all

of the state laws' applications, petitioner must show that the state and federal laws conflict *as those laws apply to petitioner*. See Pet. App. 8a-9a n.2 ("[T]here is no preemption overbreadth doctrine."); *Kansas*, 589 U.S. at 208 (assessing preemption "as applied" to particular prosecutions). To establish such a conflict, petitioner must show that its own conduct falls within the FDCA's compounding exceptions to the FDCA's general premarket-approval requirements.

As the court of appeals correctly explained, petitioner has not established that it satisfies each of Section 353b(a)'s 11 criteria for lawful compounding without premarket approval. Pet. App. 8a-9a n.2. Nor could petitioner make such a showing at this time, as indomethacin does not appear on the bulk drug substance list and indomethacin suppositories do not appear on the drug shortage list. See p. 4, *supra*; 21 U.S.C. 353b(a)(2)(A). Petitioner is therefore wrong in contending that the state-law requirements invoked by respondent will necessarily conflict with federal law by "'add[ing] to' the federal requirements for compounded drugs" or "overrul[ing] Congress's own policy judgment that premarket approval is not required" for such drugs. Pet. 19 (citation omitted). The preemption analysis ultimately may be different if some or all of the relevant state laws are found to impose requirements (or to allow exemptions) that the FDCA does not. No such issues are currently presented, however, as this case comes to the Court.

Petitioner does not engage with the existence of the state-law safe harbors, or with indomethacin's absence from the relevant FDA lists. Petitioner instead contends (Cert. Reply Br. 10) that under Section 337(a), only FDA may "decide[] whether a compounder meets

th[e] requirements" for compounding without premarket approval. But as explained, p. 12, *supra*, Section 337(a) does not bar state-law claims that incorporate federal requirements. FDA has never found that petitioner's drug meets the requirements for premarket approval, and petitioner does not claim to have sought that approval.

Petitioner is also wrong to suggest that, by declining to bring an enforcement action, FDA has implicitly authorized petitioner's compounding activities. Pet. 22-23. Such FDA inaction does not equate to an affirmative agency decision that petitioner's indomethacin suppositories are lawfully compounded. That is true even though FDA has designated indomethacin a "503B Category 1" bulk substance, meaning that FDA does not presently intend to take action against outsourcing facilities that compound using bulk indomethacin. See pp. 4-5, *supra*. That action "does not establish any rights for any person and is not binding on FDA or the public." *Interim Policy* 1. And FDA's current exercise of enforcement discretion does not make compounding with bulk indomethacin lawful; it simply reflects the agency's enforcement priorities. Petitioner's inference is especially unfounded given that FDA has not, to date, placed indomethacin on the 503B bulks list or placed indomethacin suppositories on the drug shortage list—either of which would remove the most obvious barrier to Section 353b(a)'s exemption from premarket-approval requirements.

Further, FDA does not have the resources to ensure that all compounded drugs produced across the nation comply with the requirements of Sections 353a and 353b, and the agency relies on its partnerships with States to regulate compounded drugs. See FDA, *Compounding*

Information for States (Dec. 3, 2024), https://www.fda.gov/drugs/human-drug-compounding/compounding-information-states ("States are primarily responsible for day-to-day oversight over the vast majority of the thousands of compounders in the U.S., most of which do not register with FDA.").

B. This Court's Review Is Not Warranted

Petitioner contends (Pet. 14-18) that the decision below conflicts with decisions of the First and Ninth Circuits. But petitioner overstates the conflict, and the possibility of changes in the listing status of indomethacin makes this case an unsuitable vehicle to resolve any tension among the circuits.

1. Petitioner asserts (Pet. 17) that the decision below departs from the First Circuit's decision in *DiCroce* v. *McNeil Nutritionals, LLC*, 82 F.4th 35 (2023), cert. denied, 144 S. Ct. 1382 (2024). *DiCroce*, however, did not involve a state law that mirrored federal law. *Id.* at 41 n.7. Rather, the plaintiff in *DiCroce* alleged that statements on a dietary supplement's label were misleading because those statements violated the FDCA. *Id.* at 41. The plaintiff did not identify "any basis, independent of federal labeling laws, from which [the court] could conclude that a consumer would be misled by [the supplement's] label." *Ibid.* In those circumstances, the First Circuit concluded that the plaintiff was attempting to enforce the FDCA rather than showing that particular FDCA-violating conduct also violated state tort law. *Ibid.* Here, by contrast, the state laws at issue impose independent state-law requirements that incorporate federal law, and respondent has alleged that petitioner's sales violate those state laws, not the FDCA alone. The decision in *DiCroce* therefore does not indi-

cate that the First Circuit would view respondent's state-law claims as preempted.

Petitioner also contends (Pet. 14-16) that the decision below conflicts with the Ninth Circuit's decision in *Nexus Pharmaceuticals, Inc.* v. *Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (2022). In that case, a drug manufacturer sued a registered outsourcing facility under the unfair-competition laws of several States, alleging that the facility was marketing drugs without FDA authorization in violation of state law. The drug manufacturer further alleged that the drug at issue was not lawfully compounded because it violated Section 353b's requirement that "[t]he drug is not essentially a copy of one or more approved drugs." 21 U.S.C. 353b(a)(5).

The Ninth Circuit concluded that the state-law claims were impliedly preempted. The court explained that Section 337(a) bars private enforcement of the FDCA, and that the claims would require litigation of whether the defendant's compounded drug was "essentially a copy" of the plaintiff's approved drug, which in the court's view "would amount to litigation of the alleged underlying FDCA violation even though the FDA has not itself concluded that there was a violation." *Nexus Pharmaceuticals*, 48 F.4th at 1049. The Ninth Circuit also noted that FDA had "been attentive to the difficult issues of interpreting and enforcing the 'essentially a copy' provision," and the court concluded that the determination whether to enforce that provision should be left "in the first instance to the FDA's balancing of risks and concerns." *Id.* at 1050.

While the reasoning in *Nexus Pharmaceuticals* is inconsistent with that of the Fifth Circuit below, that shallow and recent disagreement does not warrant the Court's review. As an initial matter, the Ninth Circuit's

decision in *Nexus Pharmaceuticals* is in tension with a later Ninth Circuit decision holding that the FDCA did not preempt a claim under a California law that "incorporates by reference all federal food labeling standards." *Davidson* v. *Sprout Foods, Inc.*, 106 F.4th 842, 844 (2024), cert. denied, 145 S. Ct. 1922 (2025). The court in *Davidson* recognized that private suits to enforce the FDCA itself are precluded, *id.* at 848-849, but it concluded that the plaintiffs had alleged violations of "California law * * * not the federal FDCA," *id.* at 849. The court explained that Congress had included a provision that "permitted states to adopt" standards "identical to the federal standards," and it saw "no reason * * * why Congress would permit states to enact particular legislation and then deny enforcement by their citizens." *Ibid.*; see *id.* at 850 (describing a "recent case" in which the Ninth Circuit had "reaffirmed that the FDCA does not preempt claims for violations of parallel state law duties"). A more recent Ninth Circuit opinion attempted to reconcile *Nexus Pharmaceuticals* and *Davidson* by asserting that the claim in *Davidson* did not "require litigating questions that are reserved for the FDA, because the violation was plain." *Bubak* v. *Golo, LLC*, No. 24-492, 2025 WL 2860044, at *2 (Oct. 9, 2025).

To the extent that preemption in the Ninth Circuit depends on whether an FDCA violation is plain, the claim at issue here would escape preemption under *Davidson*. Although the issue was not litigated as a part of the motion to dismiss, respondent has asserted (Br. in Opp. 10) that Section 353b does not presently exempt petitioner's indomethacin suppositories from FDCA premarket-approval requirements because indomethacin is not on the 503B bulks list and indomethacin sup-

positories are not on the drug shortage list. See 21 U.S.C. 353b(a)(2)(A). That assertion requires no expertise to adjudicate and is plainly correct. See p. 4, *supra*. The Ninth Circuit's concerns with allowing States to take on the "difficult issues of interpreting and enforcing" other Section 353b conditions are thus absent here. *Nexus Pharmaceuticals*, 48 F.4th at 1040.

By contrast, if "[t]he *Davidson* majority departed from *Nexus* and created an intra-circuit split," as one Ninth Circuit judge has concluded, see *Bubak*, 2025 WL 2860044 at *4 (Callahan, J., concurring), the Court should allow the Ninth Circuit itself to "reconcile its internal difficulties" rather than granting certiorari at this juncture, *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957) (per curiam).

2. Review is also unwarranted because indomethacin's regulatory status may soon change. FDA is in the process of deciding whether to add indomethacin to the 503B bulks list. If this Court granted review here, FDA might reach a decision on that regulatory matter while the Court was considering the merits of this case. If FDA added indomethacin to the bulks list while this case was pending before the Court, that development would materially change the nature of the parties' dispute, as respondent seeks only prospective relief and has acknowledged that it cannot proceed if petitioner's drug meets the Section 353b conditions. See Pet. App. 95a; Br. in Opp. 15-16, 23. Alternatively, if FDA decides *not* to add indomethacin to the list and ends its interim policy of declining to take action against compounding facilities that use indomethacin, the agency's decision would alleviate any perceived tension between suits like respondent's and FDA's enforcement policy.

Moreover, this case is currently at the motion-to-dismiss stage. If the Court wishes to consider the question presented, it could do so at a later stage, when FDA may have resolved indomethacin's listing status and when any other arguments regarding petitioner's compliance with Section 353b will be more fully developed and "better suited for certiorari review." *Abbott* v. *Veasey*, 580 U.S. 1104, 1105 (2017) (statement of Roberts, C.J., respecting the denial of certiorari).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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