No. 25-257

IN THE

Supreme Court of the United States

WELLS PHARMA OF HOUSTON, LLC,

Petitioner,

v.

ZYLA LIFE SCIENCES, LLC,

Respondent.

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

BRIEF FOR *AMICUS CURIAE* OUTSOURCING FACILITIES ASSOCIATION IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Food, Drug, and Cosmetics Act of 1938 ("FDCA") preempts private state-law unfair competition and consumer protection claims premised on the marketing of compounded drugs without pre-market approval.

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INTEREST OF AMICUS CURIAE[1]

The Outsourcing Facilities Association ("OFA") is the trade association representing FDA-registered 503B outsourcing facilities that focus on providing patients and healthcare providers with safe and effective compounded medications. OFA members work with patients, healthcare providers, and facilities on a daily basis to ensure the specific needs, of both providers and patients, for compounded medications are satisfied. OFA works with industry, governmental agencies, and healthcare providers to educate and advocate for outsourcing facilities and the critical need to ensure that patients and providers have access to needed medications.

OFA has a fundamental interest in the resolution of this case, and those like it, which are directed at undoing Congress's determination to permit outsourcing facilities compounding under the strict terms and conditions of federal law.

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[1] Amicus curiae OFA affirms that no counsel for a party authored this brief in whole or in part, and no one other than amicus or its counsel made a monetary contribution intended to fund the preparation or submission of the brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the intention of amicus to file this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

When Hurricane Helene rampaged through the Southeast in September 2024, it caused the flooding of a Baxter Pharmaceutical facility that manufactures sixty percent of the Nation's intravenous solutions, which are necessary for "everything from intravenous rehydration and drug delivery to peritoneal dialysis used to treat kidney failure." Beth Mole, "Helene Ravaged the NC Plant that Makes 60% of the Country's IV Fluid Supply" (Oct. 4, 2024).[2] The U.S. Food and Drug Administration's response was to call on outsourcing facilities—large-scale drug compounders strictly regulated under federal law—to help prevent a devastating shortage by stepping in to satisfy unmet demand. Legally, it did this through the exercise of "enforcement discretion," wielding the federal government's exclusive enforcement authority to temporarily authorize the manufacturing of intravenous solutions by outsourcing facilities that would otherwise be subject to sanction. *See* FDA, Temporary Policies for Compounding Certain Parenteral Drug Products: Guidance for Industry, at 3–6 (Oct. 2024).[3]

The Fifth Circuit's decision in this case, however, would expose the same facilities that responded to FDA's call to liability for violation of federal law, by approving state laws that transfer the FDA's enforcement discretion to private competitors. That decision

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[2] *Available at* https://arstechnica.com/health/2024/10/helene-ravaged-the-nc-plant-that-makes-60-of-the-countrys-iv-fluid-supply/.

[3] *Available at* https://www.fda.gov/media/182632/download (Temporary Policies).

allows state law to make a hash of federal law. According to the court below, states may enact "unfair competition" actions premised on compounders' failure to obtain FDA premarket approval for compounded drugs when federal law expressly exempts them doing so. In this, the decision upends the carefully structured federal regulatory regime governing compounding by outsourcing facilities and puts at risk patient access to needed medications produced by outsourcing facilities.

That result is at odds with Congress's judgment that the need for compounding is so urgent that preapproval should not be required as in the case of other "new drugs." Not only do compounders provide necessary pharmaceuticals during emergencies such as Hurricane Helene, but they also serve as the source of drugs tailored to the needs of individuals or small patient communities, especially children and the elderly, whose needs are not, and cannot be, met by new drug manufacturers. The need for such compounders is indisputable. To ensure safety in the compounding process, the FDCA imposes stringent requirements on outsourcing facilities, including the same manufacturing standards (known as "current Good Manufacturing Practices," or "cGMP") applicable to new drug manufacturers.

By authorizing "unfair competition" claims premised on misapplication of federal law, the decision below poses a serious threat to patient access in the six affected States, and potentially on a National basis. The costs of defending such suits will be damaging enough, but if States' adoption of federal law's preapproval requirement as part of their law, without

federal law's critical exemptions, does constitute "unfair competition," courts may enjoin the compounding of drugs necessary to public health. Indeed, the Fifth Circuit's flawed reasoning may also open new drug manufacturers to similar competitor suits. Preapproval is not the only requirement imposed by the Federal Food, Drug, and Cosmetic Act. To the extent that violations of the preapproval requirement or the Act's other requirements can also serve as the gravamen of state unfair competition suits against the manufacturers of approved drugs, enforcement discretion—which Congress exclusively vested solely in the FDA as to drugs—will become a weapon wielded by one competitor against another.

This Court's intervention is manifestly needed and critical. In reaching its decision here, the Fifth Circuit broke with two other federal courts of appeal, the First Circuit in *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35 (1st Cir. 2023) and Ninth Circuit in *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.,* 48 F.4th 1040 (9th Cir. 2022), which both squarely concluded that state unfair competition claims based on alleged FDCA violations are preempted. These cases are indistinguishable from this one in all material respects. The Court should grant the petition for certiorari and reverse the Fifth Circuit's judgment.

ARGUMENT

I. The Court's Review is Necessary To Protect Public Health

The Court must review and reverse the Fifth Circuit's decision because it contravenes Congress's

decisions to authorize the marketing of compounded drugs not subject to premarket approval and to vest enforcement discretion over federal law's regulation of compounding in the FDA alone. The decision below poses a real and serious threat to patient access and, by extension, public health.

Drug compounding is "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002) (citation omitted). As defined in the Act, virtually every such compounded medication would qualify as a "new drug" requiring FDA preapproval under FDCA Section 505.[4] Such compounded drugs may be prepared to meet the needs of only one or a handful of patients, which effectively rules out obtaining premarket approval, which takes years and costs a billion dollars or more per drug. *See* Olivier J. Wouters, Martin McKee,

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[4] "New drug" is defined as:

> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ; or
>
> (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

21 U.S.C. § 321(p).

Jeroen Luyten, "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018," 323 *J. of Am. Med. Assn.* 9 (Mar. 3, 2020, corrected Sept. 20, 2022).

Drug compounding is an essential component of public health and individual health care. *See* C. James Watson, James D. Whitledge, Alicia M. Siani, Michele M. Burns, "Pharmaceutical Compounding: a History, Regulatory Overview, and Systematic Review of Compounding Errors," 17 *J. of Med. Toxicology* 197, 205 (2021) ("[W]e must remain aware that compounding pharmacies frequently provide an essential service and poorly calibrated regulations may contribute to issues of access."). Commercially available drugs are generally manufactured for broad application. So, medications must still be tailored to meet the needs of individuals or small groups of patients in various circumstances, including:

- When a particular treatment regimen requires more than one medication in a dose;
- When a particular medication is not commercially available in the required dosage;
- When a particular medication is commercially available only in pill or capsule form, although many patients (especially those who have difficulty swallowing, the elderly, and children) require a liquid;
- When a condition is treated more effectively by medications in a topical form;
- When a patient may be allergic to one or more of the ingredients of a commercially

available medication, such as artificial dyes and flavoring, or to sugar or other sweeteners; and

- When there is a disruption in supply and/or a health care emergency, such as the COVID-19 pandemic.

See generally Watson, *supra*, at 197–98. As examples, "numerous chemotherapy regimens must be compounded for cancer treatment," and "[r]efractory neuropathic pain" is often treated with "compounded analgesic topical creams containing multiple medications not commercially available in combination." *Id.* at 198.

Another highly important benefit of drug compounding involves "medication adherence" defined as "an active, cooperative, and voluntary participation of the patient in following recommendations from a healthcare provider regarding dosing regimens." Maria Carvalho, Isabel F. Almeida, "The Role of Pharmaceutical Compounding in Promoting Medication Adherence," *Pharmaceuticals* (Aug. 31, 2022).[5] Medications that are in an easy to take form, or with a particular flavoring, can support medication adherence both in children and particularly the elderly, who may require daily doses of a number of medications for various health conditions. Here, "[p]harmaceutical compounding may reduce the medication regimen complexity by providing special drug combinations that bring together several commercial medicines in one single dosage form." *Id.* at § 3.1.2. And, of particular note, "[o]ncology and pain management are among

[5] *Available at* https://www.mdpi.com/1424-8247/15/9/1091.

those medical specialties that benefit the most from drug combinations. For instance, compounded mouthwashes for chemo-induced oral mucositis (CIOM) play a major role in the quality of life of cancer patients." *Id.*

Additionally, compounded drugs may be essential in meeting patient needs for those who require "orphan" drugs that treat rare diseases, *id.* at § 3.2.2, or medications that have been discontinued by manufacturers because of their lack of profitability: "There is a long and growing list of proprietary medicines that have been discontinued by the pharmaceutical industry, mainly for commercial reasons." *Id.* at § 3.3.2.

Congress was clearly aware of these considerations when it specifically exempted drug compounding from the FDCA's preapproval requirement. As an alternative to preapproval, Congress imposed significant regulatory requirements on both "compounding pharmacies" (generally licensed pharmacies filling individual prescriptions) and "outsourcing facilities" (which manufacture compounded drugs in bulk, without patient-specific prescriptions). Section 503A applies to compounding pharmacies and allows their compounding under the following conditions:

(1) compounding must be done for an individual patient based on a prescription indicating that a compounded medication is necessary for that patient;

(2) it must be performed by a licensed pharmacist or physician;

(3) the compounding must take place at a state-licensed pharmacy or a federal facility;

(4) FDA-authorized ingredients must be used;

(5) the compounded drug must not be the same as a drug withdrawn or removed from the market as unsafe or ineffective; and

(6) the compounder cannot compound "regularly or in inordinate amounts . . . any drug products that are essentially copies of a commercially available drug product."

See generally 21 U.S.C. § 353a(a), (b)(1). A compounding pharmacist or physician may also, even in advance of a particular prescription, produce limited quantities of a drug, but only when based on a history of receiving such prescriptions for individual patients. *See id.* § 353a(a)(2)(B).

Outsourcing facilities, such as Petitioner Wells Pharma, are subject to even stricter requirements, as their products are compounded in bulk under Section 503B. Outsourcing facilities need not be licensed pharmacies and are not required to have prescriptions for individual patients. *Id.* at § 353b(d)(4)(B)–(C). But they must comply with the same stringent manufacturing standards as new drug makers—"current Good Manufacturing Practices," or "cGMP."[6]

[6] As FDA explains:

Outsourcing facilities are also subject to federal reporting and inspection requirements. *See id.* § 353b(a) & (b).

Congress's purpose in enacting Section 503B was to "create a whole new alternative for safe sources of sterile compounded drugs that are held to a nationwide quality standard." 159 Cong. Rec. S8072 (daily ed. Nov. 18, 2013) (statement of co-sponsor Sen. Alexander); *see also id.* at S8074 (statement of co-sponsor Sen. Warner) (The Act "ensures that patients and providers have access to safe compounded drugs."). But if outsourcing facilities are subject to state lawsuits by new drug competitors, Congress's design is thwarted. Compounders would, at a minimum, have to bear the costs of defending such suits. Although the court below suggested that a defending outsourcing facility might be able to claim their FDCA exemption as an affirmative defense, *see Zyla Life Sciences, LLC v.*

> Adherence to the CGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards.

FDA, Facts About the Current Good Manufacturing Practice (Jan. 21, 2025), *available at* https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp.

Wells Pharma of Houston, LLC, 134 F.4th 326, 331 n.2 (5th Cir. 2025), there is no basis for that in the state laws at issue. They require preapproval, and it is the compounder's failure to secure such approval that is the gravamen of any such suit.[7]

II. FDA's Exclusive Enforcement Discretion is a Critical Aspect of National Health Security

The Fifth Circuit's ruling also eliminates FDA's ability to permit the compounding of necessary drugs in emergency circumstances by exercising its exclusive enforcement discretion. Congress expressly rejected both private civil actions and official state actions as mechanisms for enforcement of the FDCA's drug provisions. The statute provides that "all . . . proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). The only exception is for States, who may bring in their "own name[s] and within [their] jurisdiction proceedings for the civil enforcement, or to restrain violations, of" various enumerated provisions addressing misbranded foods. *Id.*

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[7] Five of the six states, California, Connecticut, Florida, South Carolina and Tennessee, merely reference FDCA Section 505, which contains the preapproval requirement. Colorado arguably incorporates a broader swath of federal law, providing "no person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law." Colo. Rev. Stat. § 12-280-131(1). As construed by the Fifth Circuit, however, they are the same: "As relevant here, six states have decided to mirror federal law by making it illegal to sell any new drug that has not been approved under 21 U.S.C. § 355 (the original § 505 of the FDCA)." 134 F.4th at 332 & n.3.

at § 337(b)(1). Even then, the state authorities must notify federal officials of their intent to bring an action and can proceed *only* if a federal proceeding is not brought in a timely manner. *See id*. at § 337(b)(2).

Thus, the Fifth Circuit's ruling results in the worst of all possible regulatory enforcement worlds, substituting for FDA's discretion not the enforcement discretion of state regulators, but the commercial interests of market competitors determined to protect their own bottom lines rather than public health needs. And the fact that the FDA retains authority to bring its own enforcement actions solves nothing. The Agency's enforcement discretion has been traditionally used to ensure that the FDCA's requirements are administered so as not to compromise the overall goal of meeting the needs of the patient population.

As described above, late last year the FDA addressed the emergency caused by Hurricane Helene's flooding of Baxter International's North Carolina manufacturing facility, stopping production of as much as sixty percent of the Nation's intravenous solution products. *See*, *supra*, at 2. Indeed, this closure caused "a ripple effect which . . . permeated hospitals nationwide" and could have caused "a true 'black swan' event" had Hurricane Milton, following hard on Helene's heals, closed the B. Braun facility in Daytona Beach, Florida, which was to help make-up the Baxter shortfall. *See* David Aguero and Delia Allen, "Weathering the Storm: Commentary on the Hurricane Helene IV Fluid Shortage," 29 *J. Pediatric Pharmacology and Therapeutics* 667 (Dec. 9, 2024); Fraiser Kansteiner, "B. Braun's Florida facility largely

unscathed as Hurricane Milton threatens to further upend supplies of critical IV fluids" (Oct. 10, 2024).[8]

On October 11, 2024, FDA announced release of its *Temporary Policies for Compounding Certain Parenteral Drug Products: Guidance for Industry*. This Guidance stated FDA's policy, *grounded in its FDCA enforcement discretion*, to permit both Section 503A compounding pharmacies and Section 503B outsourcing facilities to make certain drugs that are essentially copies of commercially available drugs, and compound with bulk drug substances not on FDA's list, if requirements listed in the Guidance were met. This was the case even though the normally applicable FDCA requirements, under Sections 503A, 503B, and 505, would not be met. The agency explained that, because of Helene, "hospitals and health systems may have difficulty obtaining adequate supplies of certain FDA-approved parenteral drug products" so that:

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[8] *Available at* https://www.fiercepharma.com/pharma/b-brauns-daytona-beach-facility-intact-hurricane-milton-threatens-further-upend-supplies.

Another example of a compounded product filling an immediate need is the successful effort by several Hemophilia patient advocacy groups to have FDA add a desmopressin acetate nasal spray to its National Drug Shortage List. This medication has been "an important first-line therapy for nearly three decades used in the management of bleeding and facilitating surgical procedures," which had been discontinued by its manufacturer in 2020 pending further FDA review. *See* Hemophilia Foundation of America, "Access to DDAVP Nasal Spray" (2025), *available at* https://www.hemophiliafed.org/resource/access-to-ddavp-nasal-spray/.

> as a temporary measure, FDA does not intend to take action against a State-licensed pharmacy that is not registered as an outsourcing facility, including a hospital or health system pharmacy, for providing a compounded drug to a hospital or health system without obtaining a patient-specific prescription, or for compounding a drug that is essentially a copy of a commercially available drug, if all of the [listed circumstances are present] . . . .

And,

> as a temporary measure, FDA does not intend to take action against an outsourcing facility for compounding a drug product that is essentially a copy of an approved drug, for using a bulk drug substance that is not on FDA's 503B Bulks List, or for not meeting CGMP requirements with regard to product stability testing and the establishment of an expiration date, as described below, when all of the following circumstances are present . . . .

FDA, Temporary Policies for Compounding Certain Parenteral Drug Products: Guidance for Industry, at 3–6 (Oct. 2024).[9]

FDA took similar actions at the beginning of the COVID-19 pandemic in April, 2020, issuing two policy documents: a *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised): Guidance for Industry* (Apr.

[9] *Available at* https://www.fda.gov/media/182632/download.

2020, updated May 21, 2020),[10] and a *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency: Guidance for Industry* (Apr. 2020, updated May 8, 2020).[11]

Like the FDA's Hurricane Helene emergency policies, these documents announced the Agency's enforcement intentions with respect to compounding and dispensing certain FDA-approved drugs, which increased demand and supply chain disruptions had brought into emergency shortage:

> FDA has received a number of reports related to increased demand and supply interruptions involving FDA-approved drug products used in the treatment of hospitalized patients with COVID-19. Many of these drug products are needed to support COVID-19 patients who have been intubated, or for other procedures involved in the care of such patients. Some reports involve drug products that appear on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) ("FDA's drug shortage list"). In addition, with respect to certain other drug products needed to support hospitalized COVID-19 patients but that do not appear on FDA's drug shortage list, certain

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[10] *Available at* https://collections.nlm.nih.gov/catalog/nlm:nlmuid-9918227271106676-pdf (Outsourcing Facilities Guidance).

[11] *Available at* https://downloads.regulations.gov/FDA-2020-D-1136-0011/attachment_1.pdf (Compounding Pharmacy Guidance).

> hospitals have concerns about accessing them due, for example, to regional disparities in COVID-19 infection rates, or other regional conditions that may evolve quickly during the public health emergency.

Outsourcing Facilities Guidance, *supra*, at 2; Compounding Pharmacy Guidance, *supra*, at 2.

With respect to outsourcing facilities, the Department of Health and Human Services noted in particular that under the FDCA Section 503B outsourcing facilities "may legally compound drug products that are identical or nearly identical to FDA-approved products that appear on FDA's drug shortage list,"[12] but also noted that such facilities were subject to strict statutory limitations that may prevent compounding in certain instances. Outsourcing Facilities Guidance, *supra*, at 3. Consequently, the Agency stated that:

> As a temporary measure, FDA does not intend to take action against an outsourcing facility for compounding a drug product that is essentially a copy of an approved drug, for using a bulk drug substance that is not on FDA's 503B Bulks List, or for not meeting CGMP requirements with regard to product stability testing and the establishment of an expiration date . . . .

Temporary Policies, *supra*, at 5.

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[12] HHS, Impact of Drug Shortages on Consumer Costs, at 12 (May 2023), *available at* https://www.ncbi.nlm.nih.gov/books/NBK603205/pdf/Bookshelf_NBK603205.pdf.

Concerned that registered outsourcing facilities would not be able to meet the need, FDA also permitted compounding pharmacies to make the identified drugs:

> as a temporary measure during the public health emergency related to COVID-19, or for such shorter time as FDA may announce by updating or withdrawing this guidance based on evolving needs and circumstances, FDA does not intend to take action against a pharmacy for compounding a drug that is essentially a copy of a commercially available drug, or for providing a drug to a hospital without obtaining a patient-specific prescription, if all of the following circumstances are present and the other conditions of section 503A of the FD&C Act are met.

Compounding Pharmacy Guidance, *supra*, at 4.

Under the Fifth Circuit's reasoning in this case, compounding pharmacies and outsourcing facilities in the affected states, who followed FDA's guidance to address the COVID-19 health emergency and the Hurricane Helene emergency, would nevertheless be open to state "unfair competition" claims brought by new drug manufacturers, including those who unable to meet public needs. FDA's declaration of its enforcement intent would, for all practical purposes, be nullified—as would Congress's decision to permit the compounding and sale of drugs that have not been preapproved by FDA, where the statutory requirements are satisfied.

Finally, it should also be noted that, if permitted to stand, the Fifth Circuit's ruling would equally subject new drug pharmaceutical manufacturers, like Zyla Life Services, to state unfair competition claims based on alleged FDCA violations. Once a manufacturer secures Section 505 FDA preapproval, it is nevertheless subject to continuing statutory and regulatory obligations, including monitoring and reporting requirements on safety and adverse reactions to approved drugs under Section 505, 21 U.S.C. §§ 355(k)(1), 355b; 21 C.F.R. § 314.80;[13] compliance with current good manufacturing practices, *see* 21 U.S.C. § 351(a)(2)(B);[14] reporting changes to a drug's formulation and manufacturing process, *see id.*

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[13] Once a drug is approved by FDA, the applicant must report "adverse drug experiences" to the Agency within regulatorily prescribed timeframes. 21 C.F.R. § 314.80(c). An "adverse drug experience" is defined as:

> Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

Id. at § 314.80(a). This, and other, information is ultimately fed into the FDA Adverse Event Reporting System (FAERS) database.

[14] Under this section, a drug is considered to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(B). Adulterated and misbranded drugs may not be introduced into interstate commerce. *Id.* § 331(a).

§ 356a; and stringent labeling requirements and a prohibition on misleading promotional materials, *see, e.g., id.* §§ 321(n) & 352.

The requirements applicable to pharmaceutical company advertisements offer plaintiffs a particularly rich hunting ground for competitor claims. Such advertisements are regulated under 21 U.S.C. § 352(n) which, among other things, requires that advertisements "presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner." The FDA has adopted highly detailed regulations for such prescription drug advertisements. *See* 21 C.F.R. § 202.1.

FDA believes that many manufacturers are violating these requirements. Indeed, on September 9, 2025, the FDA announced a major enforcement effort against deceptive advertising, issuing "thousands of letters warning pharmaceutical companies to remove misleading ads and issuing approximately 100 cease-and-desist letters to companies with deceptive ads." *See* FDA News Release, FDA Launches Crackdown on Deceptive Drug Advertising (Sept. 9, 2025).[15] In these letters, the Agency particularly highlighted the use of social media platforms to promote prescription medications:

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[15] *Available at* https://www.fda.gov/news-events/press-announcements/fda-launches-crackdown-deceptive-drug-advertising.

> On social media platforms, deceptive advertising is sadly the current norm. A 2024 review in the Journal of Pharmaceutical Health Services Research reveals that while 100% of pharmaceutical social media posts highlighting drug benefits, only 33% mention potential harms. Moreover, 88% of advertisements for top-selling drugs are posted by individuals and organizations that fail to adhere to FDA "fair balance" guidelines.

FDA Cease and Desist Letter to Pharmaceutical Industry (Sept. 9, 2025).[16] Under the Fifth Circuit's ruling in this case, if the six States have made the FDCA "their own," successfully eliding the FDCA's ban on private enforcement actions, then a Pandora's Box of litigation has been opened. This is not what Congress intended, and this is not what Congress did.

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The Court's intervention is crucial to protecting public health and ensuring the continuing availability of the compounded drugs on which many depend. The decision has also undermined FDA's ability to employ the exclusive enforcement discretion that Congress conferred on the agency to permit and encourage

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[16] *Available at* https://www.fda.gov/media/188616/download?attachment.

Notably, under the concurrence in *Buckman Comp. v. Plaintiff's Legal Committee,* 531 U.S. 341 (2001), if and when the FDA comes to the conclusion that a particular manufacturer has violated the FDCA's requirements, then state tort claims might be said to parallel or assist in the enforcement of federal law and avoid preemption. *See id.* at 354 (Stevens, J., concurring in the judgment).

compounding to meet acute public needs, such as in emergency situations. Additionally, the Fifth Circuit's decision created a split among the circuits, which in and of itself would justify the Court's hearing this case.

CONCLUSION

The Court should grant the Petition for Certiorari and reverse the Fifth Circuit's judgment.

Respectfully submitted,

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