No. 12-1339

IN THE

Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORP.,

Petitioner,

v.

HERBERT FUSSMAN, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF RITA FUSSMAN,

Respondent.

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

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Amici address the following questions:

(1) Whether the FDA's exclusive authority to punish violations of federal law governing the lawful marketing of prescription drugs preempts state tort law which allows the imposition of punitive damages to punish the same activity.

(2) Whether a punitive damages award imposed in connection with the marketing of an FDA-approved drug impermissibly penalizes a drug manufacturer under state law for the exercise of its federal right to market the prescription drug.

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SUPREME COURT OF THE UNITED STATES

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BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTERESTS OF *AMICI CURIAE*[1]

The Washington Legal Foundation (WLF) is a public-interest, law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited, accountable government. To that end, WLF regularly appears as *amicus curiae* before this Court in cases involving preemption issues, to point out the economic inefficiencies that often result when multiple layers of government seek to regulate the

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[1] Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days before the due date, counsel for *amici* provided counsel for Respondent with notice of intent to file. All parties have consented to the filing of this brief; letters of consent have been lodged with the Clerk.

same activity. *See, e.g., Mut. Pharm. Co., Inc. v. Bartlett*, ___ S. Ct. ___, 2013 WL 3155230 (2013); *Riegel v. Medtronic, Inc.,* 552 U.S. 312 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

The Allied Educational Foundation (AEF) is a non-profit charitable foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared in this Court on a number of occasions.

Amici are deeply concerned that individual freedom and the American economy both suffer when state law, including state tort law, imposes upon an entire industry an unnecessary layer of regulation that frustrates the objectives or operation of specific regulatory regimes, such as (in this case) the Food, Drug, and Cosmetic Act (FDCA). *Amici* are also concerned that by imposing punitive damages on a prescription drug manufacturer, the jury below essentially penalized the defendant for merely exercising its federally granted right to market a brand name prescription medication.

STATEMENT OF THE CASE

Under the Food, Drug, and Cosmetic Act (FDCA), a drug manufacturer may not market a new drug before first submitting a new drug application (NDA) to the FDA and receiving the agency's approval. *See* 21 U.S.C. § 355(a). An NDA must contain, among other things, "the labeling proposed to be used for such drug," § 355(b)(1)(F), "full reports of investigations which have been made to show

whether or not such drug is safe for use and whether such drug is effective in use," § 355(b)(1)(A), and a "discussion of why the benefits exceed the risks under the conditions stated in the labeling," 21 CFR § 314.50(d)(5)(viii) (2008). The FDA will approve an NDA only if the agency finds that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling" and that the proposed labeling is not "false or misleading in any particular." 21 U.S.C. § 355(d).

After the FDA approves a drug, the manufacturer has a continuing obligation to investigate and report any adverse events associated with the drug. *See* 21 CFR § 314.80. It must periodically submit any new information that may impact the FDA's previous conclusions about the safety, effectiveness, or labeling of the drug. *See* 21 U.S.C. § 355(k). The FDA may require post-marketing studies to further evaluate the drug's safety and efficacy. *See* 21 U.S.C. § 356b. At all times, the FDA retains continuing regulatory authority over the content and format of drug labels. *See* 21 C.F.R. § 201.57. If the FDA finds that the drug is not "safe" when used according to its label, the agency "shall" withdraw its approval of the drug. *See* 21 U.S.C. § 355(e).

Under the FDCA's regulatory regime, a drug's warning label "serves as the standard under which the FDA determines whether a product is safe and effective." 50 Fed. Reg. 7470 (1985). As the "centerpiece of risk management," the warning label communicates to healthcare practitioners the agency's formal, authoritative conclusions regarding

the conditions under which the product can be used safely and effectively." 71 Fed. Reg. 3934 (2006).

Novartis Pharmaceuticals Corporation (Novartis), manufactures the prescription drugs Aredia and Zometa—two leading FDA-approved bisphosphonates used to prevent the loss of bone mass. The FDA approved both drugs as safe and effective, specifically approving all proposed labeling, and has never undertaken an enforcement action against Novartis for mislabeling or misbranding related to Aredia or Zometa. Pet. App. 44a-45a, 67a.

In June 2001, under the care of her oncologist, Mrs. Rita Fussman began receiving Aredia infusions. Shortly thereafter, in November 2001, Mrs. Fussman's physician switched her from Aredia to Zometa, which requires a shorter infusion time. Pet. App. 69a-70a. In March 2003, shortly after having two teeth extracted, Mrs. Fussman developed a condition known as "osteonecrosis of the jaw" (ONJ). Mrs. Fussman's oncologist continued her monthly Zometa infusions through October 2004, and again from December 2004 to June 2005. *Id.* at 71a-72a. Mrs. Fussman ultimately died from cancer in 2009. *Id.* at 2a.

Respondent Herbert Fussman (Mrs. Fussman's husband and the administrator of her estate) brought suit alleging that Aredia and Zometa caused Mrs. Fussman's ONJ, and that Novartis failed to adequately warn of any ONJ risk associated with the drugs. Pet. App. 3a. Expressly relying on Novartis's alleged violations of FDA's regulatory scheme, Mr. Fussman sought both compensatory and punitive damages. *Id.* Following multidistrict

litigation proceedings, the case was remanded for trial to the Middle District of North Carolina. *Id.* Following a fifteen-day trial, the jury awarded Respondent $287,000 in compensatory damages for Mrs. Fussman's injuries, $1.00 for Mr. Fussman's loss of consortium, and $12,600,000 in punitive damages. *Id.* Applying North Carolina law, the district court reduced the punitive damages award to three times the amount of compensatory damages, or $861,000. *Id.* Accordingly, the total amount awarded to Respondent (including pre-judgment interest) was $1,258,083.19. *Id.*

Following the verdict, Novartis moved for judgment as a matter of law on the issue of punitive damages, arguing that any award of punitive damages was barred by federal preemption. Pet. App. 29a. Concluding that this Court completely foreclosed Novartis's preemption argument in *Wyeth v. Levine*, 555 U.S. 555 (2009), the district court denied the motion and entered judgment for Respondent. *Id.*

On appeal to the U.S. Court of Appeals for the Fourth Circuit, Novartis argued that the FDCA preempts the jury's award of punitive damages because the Aredia and Zometa labels fully complied at all times with FDA regulations, and because the FDA retains exclusive authority to enforce the labeling requirements of the FDCA. Pet. App. 18a. Novartis also argued that this Court's preemption analysis upholding an award of compensatory damages in *Levine* (relied on by the district court) is inapplicable to an award of punitive damages, whose sole purposes are to punish wrongdoing and deter others from similar behavior. *Id.*

The Fourth Circuit affirmed. Rather than carefully address whether state law may be used to enforce drug marketing standards despite the FDCA's exclusive grant of enforcement authority to the FDA, the panel merely relied on *Wyeth v. Levine* to reject Novartis's preemption argument. Pet. App. 18a-19a. The appeals court also failed to address whether Novartis could be punished under state law for its exercise of a federal right—the right to market Aredia and Zometa with full FDA approval. Rather, the court performed a perfunctory express preemption analysis to conclude that, if Congress had intended to preempt punitive damages, it would have expressly done so in the FDCA. *Id.*

REASONS FOR GRANTING THE PETITION

The Petition presents novel issues of exceptional importance to pharmaceutical manufacturers as well as health care consumers across the country. At issue is whether an $861,000 punitive damages award in a state-law products liability suit impermissibly conflicts with the FDCA's federal scheme by removing plenary enforcement discretion from the FDA and placing it in the hands of a jury. This case offers the Court an excellent vehicle to decide whether it is an appropriate function of juries hearing state-law causes of action to impose punishment in the form of punitive damages on a drug manufacturer who has fully satisfied the FDA's rigorous approval and labeling requirements.

Contrary to the Fourth Circuit's conclusion below, this question was *not* settled by *Wyeth v. Levine*. That case involved an award of *compensatory*

damages, which serve vastly different purposes than the *punitive* damages imposed by the jury in this case. Whereas compensatory damages are solely intended to make the plaintiff whole for any loss actually caused by the defendant, punitive damages go much further and are designed to punish the defendant's wrongdoing in much the same way as criminal penalties. This is a critical distinction in the context of the FDCA, and the Fourth Circuit's failure to carefully consider Petitioner's preemption argument warrants review by this Court.

North Carolina law is free to determine that Petitioner failed to provide adequate warning to Ms. Fussman's physician, and even to require Petitioner to pay compensation for damages proximately caused by that failure. But punitive damages awards impermissibly conflict with the FDCA's federal scheme by effectively removing enforcement discretion from the FDA and placing it in the hands of the jury. A drug manufacturer who satisfies the FDA's rigorous approval process secures the right under federal law to market its prescription drugs throughout the United States under the approved label, and only the FDA may revoke that right. Here, even though the FDA found no evidence of regulatory misconduct by Petitioner, Respondent effectively used state tort law to punish Petitioner for its exercise of a federally granted right. This it cannot do.

Review is also warranted because the decision below conflicts with this Court's holding in *Buckman v. Plaintiffs' Legal Committee*, where a unanimous Court held that federal law preempted all state-law claims that the defendant misled the FDA for the

purpose of obtaining FDA approval for its device. Here, the FDCA has established a "comprehensive scheme" of disclosure requirements as part of the approval process for any prescription drug. Respondent's punitive damages claim presents precisely the same sort of obstacle to federal policy identified by the Court in *Buckman*, but the Fourth Circuit gave no consideration to that inherent conflict in evaluating whether Congress impliedly preempted such a claim when it granted the FDA exclusive enforcement authority. If plaintiffs such as Respondent are allowed to manipulate state-law duties as a backdoor way to enforce federal regulatory requirements, *Buckman* will be rendered a dead letter.

The goals of fairness, predictability, and *stare decisis* were all injured in this case. WLF joins with Petitioner in urging this Court to grant the petition for writ of certiorari.

I. THIS CASE PRESENTS IMPORTANT QUESTIONS OF LAW NEITHER RAISED NOR ADDRESSED IN *LEVINE*

In *Wyeth v. Levine*, 555 U.S. 555 (2009), this Court affirmed a State's right, through a civil tort jury, to *compensate* its residents for injuries allegedly caused by prescription drugs. *Levine* did not consider, much less affirm, a jury's ability to *punish*, through the imposition of punitive damages, drug manufacturers for alleged misconduct in the marketing and labeling of FDA-approved prescription drugs. In fact, this Court has *never* addressed the preemption of punitive damages in pharmaceutical products liability litigation.

Nevertheless, the panel below perfunctorily concluded that the novel questions raised in this case were settled "in no uncertain terms" by this Court in *Levine*. Pet. App. 18a. Not so.

Contrary to the Fourth Circuit's view, *Levine* was by no means the last word on federal preemption in the prescription drug context. As this Court readily acknowledged earlier this week, the issue of FDCA preemption "has repeatedly vexed the Court—and produced widely divergent views—in recent years." *Mut. Pharm. Co., Inc. v. Bartlett*, ___ S. Ct. ___, 2013 WL 3155230, *12 (2013). Because the FDCA's treatment of prescription drugs includes neither an express preemption clause nor an express non-preemption clause, this Court is "left to divine Congress' will" on a case-by-case basis. *Id.* This case presents the Court with an excellent opportunity to provide lower courts with badly needed guidance regarding a frequently recurring issue.

Compensatory damages like those upheld in *Levine* serve a vastly different purpose than the punitive damages imposed by the jury in the instant case. Whereas compensatory damages "are intended to redress the concrete loss that the plaintiff has suffered by reason of the defendant's wrongful conduct," punitive damages "serve a broader function." *Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 432 (2001). Punitive damages "are not compensation for injury. Instead, they are private fines levied by civil juries to punish reprehensible conduct and to deter its future occurrence." *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 350 (1974). Indeed, punitive damages "serve the

same purposes as criminal penalties," *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 417 (2003), and "operate as 'private fines' intended to punish the defendants and to deter future wrongdoing," *Cooper Indus.*, 532 U.S. at 432. This is a critical distinction in the context of the FDCA, and the Fourth Circuit's failure to carefully consider Petitioner's preemption argument warrants review by this Court.

Even those members of the Court who have taken a somewhat narrower view of preemption have focused on the *compensatory* function of state tort claims. *See Bartlett*, 2013 WL 3155230 at *17 (Sotomayor, J. dissenting) ("[T]he legislative history of the FDCA suggests that Congress chose not to create a federal cause of action for damages precisely because it believed that state tort law would allow injured consumers to obtain *compensation*.") (emphasis added); at *21 ("New Hampshire's design-defect law did not require [Petitioner] to do anything other than *to compensate consumers* who were injured by an unreasonably dangerous drug.") (emphasis added). Indeed, the premise of Justice Sotomayor's dissent in *Bartlett* is that an award of *compensatory* damages under state tort law merely calls for a business decision by which a drug company agrees to "pay compensation as a cost of doing business," and thus should not be likened to paying a fine for the violation of a statutory mandate. *Id.* at *23, n.8. At the same time, this Court has consistently held that the imposition of *punitive* damages is directly analogous to paying a fine for a statutory violation.

The FDCA gives FDA "complete discretion" to

pursue those remedies that, in the agency's judgment, best fit a violation. *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). The FDA's exercise of that discretion "involves a complicated balancing of a number of factors which are particularly within its expertise." *Id.* at 831. By permitting what amounts to private enforcement of the FDCA under the guise of a punitive damages award, the decision below permits juries to reach judgments that differ from the FDA's as to whether drug manufacturers should be punished for alleged violations of their duties. As the Solicitor General has explained:

> If federal regulatory agencies are to perform the important functions assigned to them by Congress, they must have the ability to decide, free from hindrances imposed by state law, how best to obtain the information they need and how best to sanction those who fail to provide such information.

Buckman Br. of United States, 2000 WL 1364441, *18. Such private enforcement "distort[s] the penalty scheme established by statute," by providing remedies that Congress withheld. *Id.* at *23-24 (quotations and citations omitted). Moreover, allowing juries to substitute their judgments for FDA's as to the appropriate sanction "interfere[s] with FDA's discretion to decide which of the statutorily prescribed remedies, if any, to pursue." *Id.* Punitive damages awards thus impermissibly conflict with the FDCA's federal scheme by removing enforcement discretion from the FDA and placing it in the hands of the jury. Only discretionary review by this Court can now vindicate the important federal interests at stake.

A drug manufacturer who satisfies the FDA's rigorous approval process secures the right under federal law to market its prescription drugs throughout the United States under the approved label, and only the FDA may revoke that right. *See* 21 U.S.C. § 355. At the same time, States may not punish a drug manufacturer for the exercise of a federally granted right. "The Supremacy Clause directly forbids state action penalizing anyone for invoking a right or a procedure validly created by federal law." Laurence H. Tribe, *American Constitutional Law* § 6-29, 1182 n.11 (3d ed. 2000). This is especially true in cases where, as here, the FDA found no evidence of regulatory misconduct and never rescinded that right. *Chicago and North Western Transp. Co. v. Kalo Brick & Tire Co.*, 450 U.S. 311, 318 (1981) ("[I]t would be inconsistent with federal policy . . . if local authorities retained the power to decide whether the [railroad] carriers could do what the [Interstate Commerce] Act authorized them to do.").

Even where punitive damages are otherwise appropriate, "a State cannot punish a defendant for conduct that may have been lawful where it occurred." *State Farm*, 538 U.S. at 421. After all, "if federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both." *Levine,* 555 U.S. at 590 (Thomas, J. concurring); *see also* Caleb Nelson, *Preemption*, 80 Va. L. Rev. 225, 261 (March 2000) ("If state law purports to . . . penalize something that federal law gives people an unqualified right to do, then courts would have to

choose between applying the federal rule and applying the state rule, and the Supremacy Clause requires them to apply the federal rule.").

Unlike *Levine*, which allowed compensatory damages, it is no answer here to insist that the imposition of punitive damages under state law serves merely to "complement" the FDCA or FDA's regulations. To the contrary, this Court has consistently held that state law *penalties* are preempted even if the state law in question purports to enforce exactly the same standards for exactly the same reasons. *See, e.g., Arizona v. United States,* 312 S. Ct. 2492, 2502-03 (2012) ("Permitting the State to impose its own penalties for the federal offenses here would conflict with the careful framework Congress adopted.").

II. THE DECISION BELOW CONFLICTS WITH *BUCKMAN* BY CONDONING STATE INTERFERENCE WITH FDA'S ENFORCEMENT OF THE FDCA

This Court's review is all the more necessary because the Fourth Circuit's decision would effectively eviscerate the rule announced in *Buckman Co. v. Plaintiffs' Legal Comm.*, which held that when the FDA exercises its statutory mandate to determine that a product is on balance "safe," a State cannot countermand that determination by calling into question the manufacturer's compliance with FDA regulations. *Buckman Co.*, 531 U.S. at 348 (holding that where the FDA has struck "a somewhat delicate balance of statutory objectives" in determining that petitioner submitted a valid application to manufacture a medical device, a State

may not use common law to negate it). In *Buckman*, the Court examined the circumstances under which a products liability claim against a medical device manufacturer should be deemed impliedly preempted under conflict preemption principles. *Id.* at 348. Concluding that private jury awards would conflict with the FDA product-approval process, a unanimous Court held that federal law preempted all state-law claims that the defendant misled the FDA for the purpose of obtaining FDA approval for its device. *Id.* As the Court explained, "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.*

Here, the FDCA has established a "comprehensive scheme" of disclosure requirements as part of the approval process for any prescription drug. The FDA retains exclusive regulatory authority over the content and format of all drug labels. *See* 21 C.F.R. § 201.57. And only the FDA can impose punishment for a manufacturer's failure to comply with the agency's labeling regulations. 21 U.S.C. § 333. As the Court recognized in *Buckman*, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [law]: 'all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" 531 U.S. at 349.

Novartis argued below that, for similar reasons, Fussman's attempt to obtain punitive damages for Novartis's alleged violations of FDA regulations is impliedly preempted by the FDCA.

Here, as in *Buckman*, "we have clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government." *Buckman Co.*, 531 U.S. at 352. Accordingly, allowing a jury to award punitive damages under State tort law interferes with Congress's "delicate balance of statutory objectives" by placing enforcement discretion in the hands of private tort plaintiffs. *Id.* at 348. After all, determining whether to punish manufacturers of products whose design and labeling have been expressly approved by a federal agency "is hardly 'a field which the States have traditionally occupied." *Buckman*, 531 U.S. at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Review is thus warranted to address the conflict between *Buckman* and the decision below.

Sidestepping *Buckman* entirely, the Fourth Circuit simply relied on *Wyeth v. Levine* to reject Novartis's preemption argument out of hand. Pet. App. 18a-19a. In doing so, however, the Fourth Circuit failed even to address the pivotal issue in any implied conflict preemption analysis—whether the state action interferes or otherwise "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Fussman's punitive damages claim presents precisely the same sort of obstacle to federal policy identified by the Court in *Buckman*, but the Fourth Circuit gave no consideration to that inherent conflict in determining whether Congress impliedly preempted such a claim when it adopted the FDCA and granted

the FDA exclusive enforcement authority.[2] In light of *Buckman*, it would be highly anomalous to conclude that Congress preempted state-law liability for intentionally (and fraudulently) withholding information from the FDA, 531 U.S. at 348, but not for negligently failing to disclose the same information to the agency.

Fussman does not contend that Novartis's duty to submit reports to the FDA on the risk of ONJ exists independently of federal law. Rather, as the Petition effectively demonstrates, Fussman seeks to use North Carolina tort law to punish Novartis's alleged noncompliance *with federal law*:

> Respondent's punitive damages demand at trial rested heavily on the argument that [Novartis] has violated various FDA regulations in its labeling and marketing of Aerdia and Zometa. Respondent presented as his opening expert witness a former FDA employee, Dr. Susan Parisian, who was allowed to testify as an expert "concerning the general FDA regulatory requirements, and the procedures and any compliance that would

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[2] *Cf. Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) (holding that where the EPA has struck "the balance of public and private interests so carefully addressed by" the federal permitting regime for water pollution, a State may not use nuisance law to "upse[t]" it); *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 321 (1981) (holding that where the ICC has struck a "balance" between competing interests in permitting the abandonment of a railroad line, a State may not use statutory or common law to negate it).

> have been expected and required of the Defendants as to those regulatory requirements."

Pet. 17 (citing Pet. App. 58a). Indeed, Fussman's punitive damages claim hinged on a variety of alleged FDA-regulatory violations by Novartis, including (1) Novartis's alleged failure to provide the FDA with an animal study purportedly related to the risk of ONJ, Pet. App. 60a-61a; (2) Novartis's alleged failure to provide the FDA with information about osteopetrosis, a separate medical condition purportedly related to the risk of ONJ, *id.* at 61a; (3) Novartis's alleged failure to report to the FDA various claimed safety signals related to the risk of ONJ, *id.* at 61a-63a; and (4) Novartis's alleged failure to inform the FDA of certain comments Novartis received from members of an outside advisory group regarding the risk of ONJ, *id.* at 63a-64a.

North Carolina law is free to determine that Petitioner failed to provide adequate warning to Ms. Fussman's physician, and even to require Petitioner to pay compensation for damages proximately caused by that failure. But *Buckman* makes clear that any claim for punitive damages that is based on the federal duties Novartis owes to the FDA is impliedly preempted because it interferes with the FDA's exclusive authority to enforce the FDCA. As in *Buckman*, Fussman's theory of liability in this case turns on the claim that Novartis was obligated to disclose certain information to the FDA but failed to do so. Because North Carolina tort law is not concerned with a drug manufacturer's communications to the federal government about its

labeling, any claim arising from a "failure to submit reports to the FDA that the FDA requires is arguably a species of fraud on the agency" and is foreclosed by *Buckman*. *See Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012).

Furthermore, such private enforcement would impose prohibitive costs on manufacturers that would likely discourage the development of new, life-saving drugs. "As a practical matter, complying with FDA's detailed regulatory regime in the shadow of 50 State's tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA." *Buckman*, 531 U.S. at 350. If plaintiffs such as Fussman are allowed to manipulate state-law duties as a way to enforce federal regulatory requirements, *Buckman* will be rendered a dead letter.

In sum, review is warranted to resolve the conflict between *Buckman* and the decision below and to determine whether the Fourth Circuit's endorsement of what amounts to private enforcement of the FDCA, through the imposition of punitive damages, effectively nullifies Congress's unspoken but implied intent to preempt litigation that "would exert an extraneous pull on the scheme established by Congress." *Id.* at 353.

CONCLUSION

For the foregoing reasons, *amici curiae* Washington Legal Foundation and Allied Educational Foundation respectfully request that the Court grant the Petition.

Respectfully submitted,

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