No. 13-956

IN THE
Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC., BARR PHARMACEUTICALS LLC, BARR LABORATORIES, INC., AND SUN PHARMACEUTICAL INDUSTRIES, INC. (F/K/A CARACO PHARMACEUTICAL INDUSTRIES, LTD.),

Petitioners,

v.

THE SUPERIOR COURT OF ORANGE COUNTY (OLGA PIKERIE, *Plaintiff and Real Party in Interest*),

Respondent.

On Petition for Writ of Certiorari to the Court of Appeal of California For The Fourth Appellate District

SUPPLEMENTAL BRIEF

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations and Rules

Other Authorities

INTRODUCTION

Dozens of generic manufacturers now have filed four petitions from state intermediate and supreme court decisions that allow more than 2500 plaintiffs' "failure-to-update" claims to proceed. *See also* Nos. 14-544, 14-705, 14-711. The government likes that result, so it says the writ should be denied even though the federal and state appellate courts expressly disagree with each other, and even though thousands of additional "failure-to-update" claims remain pending nationwide.

Neither the government's jurisdictional objections nor its position on the merits provide any basis for avoiding the open split of authority on these issues, whether here or in the companion cases. Indeed, the government previously advocated—successfully—that *certiorari* be granted in materially identical circumstances. Given the need for clarity on these unsettled issues, which control the disposition of thousands of pending cases, *certiorari* should be granted.

ARGUMENT

A. This Court Has Jurisdiction.

The government's jurisdictional objections are unavailing. Though petitioners raise preemption claims alleging the impingement of significant federal interests, the government asserts that *Cox* does not apply because deferring review would not "'seriously erode federal policy.'" SG Br. 11 (quoting *Cox Broad. Corp. v. Cohn*, 420 U.S. 469, 483 (1975)). In its words, "the bare fact that a preemption defense is asserted" is insufficient. *Id.* However, petitioners are not relying on "the bare fact" of their preemption

defense, but on *Buckman*'s recognition that Congress barred private parties from "fil[ing] suit for noncompliance" with the FDCA because such lawsuits undermine FDA's exclusive authority to pursue such claims. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 & n.4 (2001) (citing 21 U.S.C. § 337(a)).

The government says those concerns have no immediacy because damages verdicts can be reversed after final judgment. SG Br. 12-13. Yet that equally was true of any workers' compensation award in *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 178 (1988), or damages award in *Belknap, Inc. v. Hale*, 463 U.S. 491, 497 (1983). Both likewise could have been overturned after final judgment.

Moreover, the government misunderstands the asserted interest. Petitioners' position (and *Buckman*'s) is that federal law bars private parties from attempting to enforce the FDCA by filing such claims: "[A]ll such 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); *see also Buckman*, 531 U.S. at 352 ("[Section 337(a) is] clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government."). Private pursuit of such claims thus offends federal policy no less than letting state courts hear claims that allegedly belong before the NLRB, *Belknap*, 463 U.S. at 497 n.5, or an arbitrator. *Preston v. Ferrer*, 552 U.S. 346 (2008).

The government ultimately says petitioners are wrong "that *Buckman* broadly bars tort actions under state law that parallel duties under the FDCA." SG Br. 12 (citation omitted). But

disagreement *on the merits* is no impediment to *jurisdiction*—as *Belknap* made clear when it *rejected* a preemption defense. 463 U.S. at 497 n.5 ("That we affirm rather than reverse … is not tantamount to a holding that we are without power to render such a judgment.").

The government ultimately claims the appellate court "addressed only two of the bases for rejecting petitioners' demurrer." SG Br. 10. But those were the only two bases *the trial court* articulated. App.30a (identifying only plaintiffs' claims for "failure to timely make FDA labeling changes and [failure] to communicate beyond the labeling" as "areas of conduct which appear not to be preempted") (citations omitted); *id.* (citing Compl. ¶¶ 119, 122, 123, 125-27, which allege failure-to-update-or-otherwise-communicate, as alleging claims that "are not preempted"). That is why the government acknowledges that all asserted claims "are supported by the same underlying factual allegations against which petitioners have asserted their preemption defenses." SG Br. 10 (citation omitted). A favorable judgment thus would terminate this litigation—which explains the trial court's certification that "[a]ppellate resolution of the controlling question of law relating to federal preemption may materially advance *to the conclusion of litigation*." App.32a.[1]

Finally, the government notes the California Supreme Court declined discretionary review. SG Br. 9, 18, 22-23. But this Court often reviews state appellate-court decisions after discretionary review is denied—including, *at the government's urging*, in

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[1] All emphases added.

preemption cases from the very court whose decision is challenged here. Br. for the United States, *Williamson v. Mazda Motor of N. Am., Inc.*, No. 08-1314 (Apr. 23, 2010), *17; *see also* Pet. Reply 1-2, 4 (collecting authorities). That the California Supreme Court denied review after three of its seven justices recused is no reason to dodge the acknowledged split on the question presented here (and/or in Nos. 14-544, 14-705, and 14-711).

This Court has jurisdiction.

B. These Issues Warrant Review.

1. The Lower Courts Are Split.

The government initially says the lower courts are not divided on the question presented. SG Br. 18-19. That surely would surprise the courts that let these claims proceed, since they *expressly* reject the state and federal decisions which bar these claims. App.28a ("We acknowledge a disagreement with our analysis in the opinions of … other courts."); *In re Reglan Litig.*, 2014 WL 5840281, *5-*6 (N.J. Super. A.D. Nov. 12, 2014) ("Some courts have followed the Fifth Circuit's reasoning in *Morris*. *See, e.g.*, *Guarino v. Wyeth, LLC*, 719 F.3d 1245 (11th Cir. 2013); *Dietrich v. Actavis, Inc.*, 138 So.3d 1163 (Fla. Dist. Ct. App. 2014). We are convinced, however, that the reasoning in *Fulgenzi* is more persuasive.").

The government nonetheless argues that in the expressly-repudiated Fifth Circuit cases, "the plaintiff failed (or arguably failed) even to plead a claim based on … failure to update." SG Br. 19. But those plaintiffs were seeking leave to assert failure-to-update claims, and the court denied the requests as "futile" because federal law bars such claims.

Morris v. PLIVA, Inc., 713 F.3d 774, 777 (5th Cir. 2013) (citing *Buckman* and § 337(a)); *see also Johnson v. Teva Pharms. USA, Inc.*, 758 F.3d 605, 611-12 (5th Cir. 2014); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 474-75 (5th Cir. 2014). To the extent the government suggests those decisions might not bind the Fifth Circuit, SG Br. 19, the Fifth Circuit disagrees. *Johnson*, 758 F.3d at 611-12 ("This claim is controlled by *Morris* and *Lashley*…. This claim is also controlled by *Morris*.").

The government next claims that "standing alone" the Fifth Circuit's holdings perhaps "could be understood" as addressing claims brought directly under the FDCA, not state law. SG Br. 19. But the Fifth Circuit's words cannot be understood in a vacuum because they were not issued in one. They considered and rejected the plaintiffs' repeated invocation of *state law*. *See* Plaintiffs-Appellants' Br., *Morris*, 2012 WL 1965532, *33 ("Nothing in the FDCA denies *a State* the right to provide a traditional damages remedy for violations of *common law duties* when those duties parallel federal requirements."); *id.* at *37-38 ("[A]ny *state law cause of action* that establishes liability [where] federal law would consider the drug misbranded are not preempted."); Appellant's Reply Br., *Johnson*, 2013 WL 787731, *21-22 ("[A]ny claim *brought under Louisiana law* that would impose liability where the drugs were misbranded under federal law … would not be preempted.").

Finally, the government says the Fifth Circuit's holdings are too "conclusory and unexplained" to warrant review. SG Br. 19. But the fact that the Fifth Circuit did not consider this a difficult question

after considering the arguments made by some of these same petitioners is no reason to avoid reviewing the California court's explicit break from its fellow appellate courts.

As for the California court's fallback position that plaintiffs can pursue claims based on petitioners' failure to send "Dear Doctor Letters," App.26a-27a, the government concedes that its holding split from the national consensus. SG Br. 22 (citing *Germain v. Teva Pharms. USA, Inc.*, 756 F.3d 917 (6th Cir. 2014); *Guarino*, 719 F.3d at 1249; *Morris*, 713 F.3d at 777); *see also Brinkley v. Pfizer, Inc.*, 2014 WL 6765126, *4 (8th Cir. Dec. 2, 2014); *In re Darvocet*, 756 F.3d 917, 932-33 (6th Cir. 2014); *Johnson*, 758 F.3d at 612; *Lashley*, 750 F.3d at 474-75; *Franzman v. Wyeth LLC*, __ S.W.3d __, 2014 WL 4210207, *11 (Mo. Ct. App. Aug. 26, 2014); *but see Hassett v. Dafoe*, 74 A.3d 202, 216 (Pa. Super. Ct. 2013), *petition for cert. filed* No. 14-705; *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80, 94 (Pa. Super. Ct. 2013), *petition for cert. filed* No. 14-711.

Instead, the government asserts that these many courts—including every federal appellate court—both misconstrued federal law and "erred in their reading of *Mensing*." SG Br. 22. Yet the government inexplicably suggests that the writ should be *denied*. *Id*. at 23. We would draw the opposite conclusion, as do this Court's rules. S. Ct. R. 10(c) (*certiorari* warranted where "a state court or a United States court of appeals … has decided an important federal question in a way that conflicts with relevant decisions of this Court").

2. The Government's Defense Of The California Decision Is Unpersuasive.

The government's agreement with the California court is no reason to deny review. It instead ensures that both sides will be well-represented here. That said, the government's merits arguments are unavailing.

It first argues that *Buckman* is limited to claims asserting fraud on the government. SG Br. 14. That narrow view ignores *Buckman*'s repeated reliance on § 337(a)—which governs the entire FDCA, not just its anti-fraud provisions. *Buckman*, 531 U.S. at 352 (citing § 337(a)); *id.* at 349 n.4 (same). Indeed, the government's position highlights the broader split over *Buckman*, since many appellate courts apply *Buckman* to non-fraud claims. Pet. 25-28 (collecting cases). The government ignores those cases, but its apparent rejection of them only confirms the need for this Court's clarification.

The government next asserts that *Buckman* is distinguishable because it purportedly did not involve a state-law duty "that would exist even absent the FDCA." SG Br. 14. That is incorrect. As the Petition explained, the *Buckman* claims invoked state common-law principles that long predated the FDCA—*i.e.*, the rule that Party A is liable to Party C where A defrauds Party B while knowing that B will rely on the fraudulent representation to C's detriment. Pet. 26-27 (quoting *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 822, 826-27 (3d Cir. 1998) (citing *Restatement (Second) of Torts* §§ 310, 525 (1977)). That well-settled tort governs an array of conduct that is unrelated to the FDCA—like real estate deals, car sales, or the lending of defective

goods. *Restatement (Second) of Torts* §§ 310-11, 525 (illustrations).

The problem in *Buckman* thus was not the lack of a preexisting common-law tort. It was that the claims *in substance* (if not *form*) sought to enforce the FDCA: Their genesis was an alleged violation of a federal duty imposed by the FDCA, and as the government now admits, "enforcement of the FDCA is … vested exclusively in the United States." SG Br. 14. Accordingly, *Buckman* turned on a variant of the familiar distinction between facial and as-applied challenges: While common-law claims are not preempted *categorically*, they are barred *when targeted at* alleged FDCA violations since FDA alone patrols that domain. That principle resolves both *Buckman* and this case: Whether framed as common-law fraud (yet targeted at fraudulent statements that allegedly violated the FDCA) or negligence (yet targeted at alleged violations of the FDCA's federal duty of sameness), slapping a state-law title on a given claim does not change its federal character.

The appellate court's characterization of plaintiffs' contrived "failure-to-update" claim as one for negligence *per se* resolves any doubt. Pet. 25-27. The government, however, asserts that "'a complaint alleging a violation of a federal statute as an element of a state cause of action' is still a state-law … claim." SG Br. 17 (quoting *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 817 (1986)). Of course it is, just like the *Buckman* claims remained state-law claims. That has implications for removal, *Merrell Dow*, 478 U.S. at 817, but no bearing on the preemption inquiry (as *Buckman* proves).

Nor is it relevant that "California's *per se* negligence doctrine … merely establishes a rebuttable presumption of negligence." SG Br. 17 (citing *Ramirez v. Nelson*, 188 P.3d 659 (Cal. 2008)). That defendants can rebut such claims with a "justification or excuse" for the alleged FDCA violation does not make the alleged FDCA violation any less essential an element of the claim. *Ramirez*, 188 P.3d at 665 (collecting cases). That is precisely what *Buckman* found problematic. 531 U.S. at 353 (finding preemption because "the existence of these federal enactments is a critical element").

The government's invocation of *Wyeth v. Levine*'s statement that "'state tort suits … provide incentives for drug manufacturers to disclose safety risks,'" SG Br. 16 (quoting 555 U.S. 555, 579 (2009)) (alteration omitted), is puzzling since *Mensing* held those considerations have no force in the generic-drug context. 131 S. Ct. at 2581. And it is doubly misplaced since *Wyeth* had no occasion to address *Buckman*: Petitioners' *Buckman* defense was not raised there because Ms. Levine was not enforcing federal *requirements*. Instead, *Wyeth* turned on the fact that "the federal regulations applicable to Wyeth *allowed* the company, *of its own volition*, to strengthen its label in compliance with its state tort duty." *Id.*

Finally, the government asserts that "failure-to-update" claims would not "impinge on FDA's enforcement discretion" because they "align with FDA's priorities." SG Br. 18. So too in *Buckman*: FDA hardly wants to be defrauded, so incentivizing truthfulness would "align with FDA's priorities." Yet as the government explained there, that superficial

congruence of interests does not change the fact that private actions disrupt FDA's enforcement discretion by substituting jury determinations for the Agency's and eliminating FDA's ability to calibrate sanctions. Pet. 29-30 (quoting Br. for the United States as *Amicus Curiae*, *Buckman* (No. 98-1768) ["*Buckman* Br."], 2000 WL 1364441, *23-*24).

The government now says its prior concerns were limited to "fraud-on-the-FDA claims." SG Br. 15 n.2. But it never explains *why* the concerns it expressed in 2000 (in *Buckman*) and 2007 (in *Warner-Lambert v. Kent,* 552 U.S. 440 (2008), *see* Br. for the United States as *Amicus Curiae*, 2007 WL 4218889, *20-*21 (Nov. 28, 2007), are inapplicable here. Allowing these claims equally would "permit juries in different States to reach judgments that differ from FDA's," "impose massive liability, when FDA would not find any misconduct," "substitute their judgments for FDA's," and otherwise "interfere with FDA's discretion to decide which … remedies … to pursue." *Buckman* Br. 23-24 (quotation omitted). Those consequences may concern this Administration less than its predecessors, but Congress and this Court said they matter.

The government's defense of the California court's Dear Doctor holding fares no better. It first distinguishes *Mensing* because "the proposed letter" there sought to provide additional warnings rather than repeat the already-approved warnings. SG Br. 21. But there was no "proposed letter" in *Mensing*, as those plaintiffs forcefully asserted: "Especially at the motion to dismiss stage, the Court must assume that the Defendants could have drafted a letter that would not [violate federal law]." Br. of Respondents,

Mensing, 2011 WL 686400, at *37. Yet *Mensing* rejected plaintiffs' assertion that they could contrive a letter that a generic manufacturer unilaterally could have sent without violating the sameness rule; it held that "federal law pre-empts these lawsuits," and so barred continued pursuit of that theory. 131 S. Ct. at 2581.

The government's real position is thus that *Mensing* itself erred—along with every federal court that since has addressed this issue. SG Br. 22. Yet it is the government that mischaracterizes the regulatory framework. Though it claims a generic manufacturer's Dear Doctor letter must be merely "consistent with and not contrary to" any labeling approved for the branded equivalent, *id.* 21, FDA's regulations actually provide that communications regarding "warnings, hazards, contraindications, side effects, and precautions" must be "*the same in language and emphasis* as labeling approved … under [21 U.S.C. § 355]." 21 C.F.R. § 201.100(d)(1). Dear Doctor letters, however, are intended precisely *to emphasize* warnings and other safety-related information. If generic manufacturers sent such letters without a corresponding communication from the brand, they plainly would violate that rule. *Morris*, 713 F.3d at 777; *Guarino*, 719 F.3d at 1249; *Brinkley*, 2014 WL 6765126, *4.

The government's argument is especially troubling not only because it misquotes the relevant regulation, but because it threatens to neuter this vital communication tool. Such letters typically are reserved for critical new information—like disclosing life-threatening adverse reactions or subpopulations at special risk. Indeed, given the gravity of typical

Dear Doctor letters, FDA's regulations specify that "such mail should be distinctive in appearance so that it will be promptly recognized and read." 21 C.F.R. § 200.5. These letters thus are intended to be rare: FDA expects *the entire pharmaceutical industry* to issue only 30 such letters from 25 manufacturers annually, an expectation that is irreconcilable with plaintiffs' insistence that every generic manufacturer must send such letters anytime the branded labeling changes. FDA, *Draft Guidance for Industry and [FDA] Staff on Dear Health Care Provider Letters*, 78 Fed. Reg. 41064, 41065 (July 9, 2013).

Plaintiffs' contrived state-law claims thus would seriously undermine such communications. Labeling changes are frequent: Between November 25 and December 18, 2014, FDA approved *85 changes* from dozens of companies. FDA, New and Generic Drug Approvals, *available at* http://tinyurl.com/FDA-Labeling-Revisions. If state law can require Dear Doctor letters about every change, providers could receive hundreds of letters *every month*—greatly diminishing their impact on busy doctors. It is hard to imagine that any physician would read them all, no matter how "distinctive" their appearance. 21 C.F.R. § 200.5. In reality, they would not be distinctive at all, and the truly important Dear Doctor letters—from brand companies, providing critical new safety information—would be lost in the deluge, to the detriment of patients and healthcare providers alike.

CONCLUSION

This Court should grant the petition and reverse.

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Respectfully submitted,

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