No. 16-684

IN THE

Supreme Court of the United States

IN RE REGLAN LITIGATION

PLIVA, INC.; BARR PHARMACEUTICALS, LLC;
BARR LABORATORIES, INC.; WATSON LABORATORIES, INC.;
TEVA PHARMACEUTICALS USA, INC.,
Petitioners,

v.

PHYLLIS KOHLES ET AL.,
Respondents.

On Petition for Writ of Certiorari to the Supreme Court of New Jersey

REPLY BRIEF OF PETITIONERS

JAY P. LEFKOWITZ
Counsel of Record
STEVEN J. MENASHI
ELLIOT C. HARVEY SCHATMEIER
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800
lefkowitz@kirkland.com
smenashi@kirkland.com
elliot.hs@kirkland.com

Counsel for Petitioners

[*Additional Counsel Listed on Signature Page*]

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

REPLY BRIEF OF PETITIONERS

Respondents deny there is a circuit split on the question presented. Yet the New Jersey Supreme Court explicitly acknowledged that split, agreeing with the Sixth Circuit and disagreeing with the Fifth. App. 33a. That division produces different results in different jurisdictions, and numerous courts have acknowledged the growing conflict.

While Respondents do not dispute that the preemption question presented by this petition is "an issue separable from the merits and ripe for review in this Court," they assert this Court lacks jurisdiction because the decision below does not "seriously erode federal policy." This Court has explained, however, that serious erosion of federal policy occurs when state courts entertain claims that federal law bars them from hearing. That is what the New Jersey Supreme Court allowed here. Congress expressly provided that all actions to enforce the federal Food, Drug, and Cosmetic Act (FDCA) must be brought by the federal government rather than by private litigants. 21 U.S.C. § 337(a). The New Jersey Supreme Court nevertheless held that private tort suits based on alleged violations of the FDCA's labeling provisions may proceed. Withholding review of the question presented, therefore, will seriously erode the federal policy vesting exclusive enforcement authority in the federal government.

Respondents insist that this Court should defer to the FDA's interpretation of its own regulations. Yet no regulatory interpretation is at issue. Everyone agrees that generic drug manufacturers could have implemented the label changes. The only ques-

tion is whether the federal statute vesting exclusive enforcement authority in the federal government prohibits private litigants from pursuing suits that seek to impose liability for purported violations of the FDCA. On that question, the FDA receives no deference. "Although we defer to the agency's interpretation of its regulations, we do not defer to an agency's ultimate conclusion about whether state law should be pre-empted." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 n.3 (2011).

Respondents argue that review should be denied because the issue "may largely be mooted" by the settlement of some claims. But their account of the proposed settlement is overstated and speculative. There is no mootness problem here—now or in the foreseeable future. Finally, Respondents' purported "prudential considerations" do not counsel against review.

A. This Court Has Jurisdiction.

As the Petition explained, this Court has jurisdiction under *Cox Broad. Corp. v. Cohn*, 420 U.S. 469 (1975). *See* Pet. 31-33. Respondents' only counterargument is that this case does not present circumstances in which the refusal "to review the state court decision might seriously erode federal policy." *Cox*, 420 U.S. at 483; *see* BIO 9-10. That assertion is baseless. Respondents rely on this Court's statement that the fourth *Cox* category does not apply where "petitioner can make no convincing claim of erosion of federal policy that is not common to all decisions rejecting a defendant's *Batson* claim." *Johnson v. California*, 541 U.S. 428, 430 (2004). This case does not involve a *Batson* claim or, more broadly, an indi-

vidualized application of a federal standard. Rather, the ruling authorizes a wide class of private litigants to pursue lawsuits attempting to enforce the FDCA—claims Congress explicitly barred.

The threat to federal policy in this case parallels the examples of erosion of federal policy this Court identified in *Cox*. This Court found jurisdiction in a case where "postponing review would seriously erode the national labor policy requiring the subject matter of respondents' cause to be heard by the [National Labor Relations] Board, not by the state courts." *Cox*, 420 U.S. at 483 (quoting *Local No. 438 Constr. & Gen. Laborers' Union, AFL-CIO v. Curry*, 371 U.S. 542, 550 (1963)). The Court likewise found jurisdiction where defendants argued that "a special federal venue statute immunized them from suit" in the forum because "it would serve the policy of the federal statute 'to determine now in which state court appellants may be tried rather than to subject them ... to long and complex litigation which may all be for naught if consideration of the preliminary question of venue is postponed until the conclusion of the proceedings.'" *Id.* at 483-84 (quoting *Mercantile Nat'l Bank at Dallas v. Langdeau*, 371 U.S. 555, 558 (1963)).

As these and other examples make clear, federal policy is seriously eroded whenever a state court entertains a claim that federal law directs should not be entertained in that state court.

That is so here. A federal law, 21 U.S.C. § 337(a), provides that "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the FDCA. *Buckman Co. v.*

Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001) (citing § 337(a)). The New Jersey Supreme Court—in contravention of this federal policy—held that the state courts may nevertheless entertain suits by private litigants for violations of the FDCA's labeling provisions. Allowing these cases to proceed would seriously erode the federal policy that "all 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).

The federal statute bars private parties from pursuing these claims at all—not merely from collecting damages after otherwise-forbidden trial proceedings. Were it otherwise, the statutory bar would produce an absurdity: defendants could be subjected to the burdens of private-party litigation that, as here, may involve hundreds of individual plaintiffs' claims even though no recovery is possible. Like the examples identified in *Cox*, the federal statute functions like a procedural bar that prevents the state court from entertaining the claims. The appropriate time to enforce it is when the suit is brought—not years later when the federal policy vesting exclusive enforcement authority in the federal government has already been undermined. *See Buckman*, 531 U.S. at 352 ("Congress intended that the [FDCA] be enforced exclusively by the Federal Government.").

Respondents do not—and cannot—dispute that "the power of the state court to proceed in the face of the preemption claim" is "an issue separable from the merits and ripe for review in this Court." *Cox*, 420 U.S. at 483. *Cox* emphasizes that considering such a preemption claim is especially important

"when postponing review would seriously erode" a federal policy that such claims are procedurally improper and should not be entertained in that court at all. *Id.* That is this case.

B. There Is An Entrenched Circuit Split On The Question Presented.

Respondents assert that the New Jersey Supreme Court's decision implicates no division of authority among the lower courts. BIO 11-14. Even the New Jersey Supreme Court recognized that is not so. In its decision, the court rejected the Fifth Circuit's position in *Morris v. PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013), and adopted the Sixth Circuit's position in *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013). *See* App. 33a ("We do not find *Morris* persuasive. Instead, we join those courts, such as the Sixth Circuit in *Fulgenzi,* that have concluded that federal preemption does not apply to failure-to-warn claims.").

The Seventh Circuit also noted the "split in authority as to whether federal law preempts state law failure-to-update claims." *Wagner v. Teva Pharm. USA, Inc.*, 840 F.3d 355, 359 (7th Cir. 2016); *see also id.* at 359 n.1 (observing that "the Eighth Circuit noted the circuit split" on the same issue). District courts within the Fifth Circuit follow *Morris* in holding that failure-to-update claims are matters of federal rather than state law. *See, e.g.*, *Garza v. Wyeth LLC*, No. 2:12-CV-198, 2015 WL 364286, at *2 (S.D. Tex. Jan. 27, 2015) ("From *Morris* through *Johnson*, the Fifth Circuit has been consistent: 'a claim that [the generic manufacturer] breached a federal labeling obligation sounds exclusively in federal (not

state) law, and is preempted.'"). Courts outside the Fifth and Sixth Circuits recognize the split and choose one side or the other. *See* Pet. 19-22; *see also Teva Pharm. USA, Inc. v. Superior Ct.*, 217 Cal. App. 4th 96, 114 (2013) ("We respectfully believe *Morris v. PLIVA, Inc.* was incorrectly decided.").

As Respondents would have it, all those courts are mistaken and there is no split after all. Respondents insist that the Fifth Circuit never decided the issue but "simply found" that the plaintiffs' pleadings were inadequate. BIO 13. The Fifth Circuit did say in *Morris* that "no such claim appears in Appellants' live pleading," but it went on to hold that "any amendment would be futile" for two independent reasons. 713 F.3d at 777. First, a failure-to-update claim would be "logically incoherent." *Id.* Second, such a claim would be preempted under 21 U.S.C. § 337(a) and *Buckman*. The court said it directly: "a claim that PLIVA breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted." *Morris*, 713 F.3d at 777. The Fifth Circuit subsequently reaffirmed that independent holding in *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475 (5th Cir. 2014), and again in *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 612 (5th Cir. 2014). Other courts have adopted it as well. Pet. 19-20.

Respondents fleetingly acknowledge those holdings but argue the decisions only "noted the undisputed proposition that, under 21 U.S.C. § 337(a), plaintiffs could not sue for a violation of the FDCA." BIO 13. That "undisputed proposition" hardly helps Respondents because, in sum and substance, their

failure-to-update claims *are* claims "for a violation of the FDCA." *See* Pet. 5 n.2. That is precisely what the Fifth Circuit correctly recognized—in rejecting failure-to-update claims that are indistinguishable from those Respondents assert here—and the court below failed to recognize, deepening the conflict that this Court should resolve.

Respondents' argument that the Fifth Circuit never decided the issue is frivolous. The claim that the New Jersey Supreme Court allowed in this case would be dismissed in the Fifth Circuit. *Garza*, 2015 WL 364286, at *3 ("[T]he *Lashley*/*Del Valle* trio of cases requires dismissal of [a plaintiff's] failure to update theory.").

C. The FDA's Interpretation of Federal Regulatory Requirements Is Not At Issue.

Respondents note that an amicus brief in a different case "expressed the FDA's view" that "federal regulations permitted the generic drug company defendant to strengthen its warning to match that of the RLD through the CBE process without prior FDA action." BIO 15. That position is irrelevant here because no one disputes that generic drug manufacturers must update their labels to match that of the RLD. Rather, Petitioners argue that actions to enforce the FDCA's labeling provisions must be brought by the federal government and cannot be brought by private parties. *Buckman*, 531 U.S. at 352 (citing 21 U.S.C. § 337(a)). Respondents miss this essential point.

This case therefore resembles *Buckman*. In *Buckman*, no one disputed that federal regulations

allowed medical device manufacturers to disclose all relevant information to the FDA. *See Buckman*, 531 U.S. at 345-46 (noting federal disclosure requirements). Even so, this Court held that private-party claims premised on the violation of federal disclosure requirements were preempted—not because it was impossible for a defendant to comply with those requirements but because enforcing those requirements was the exclusive province of the federal government, specifically the FDA. *Id.* at 352-53 (holding that "claims arising from violations of FDCA requirements" are preempted because litigation based on claims in which "the existence of these federal enactments is a critical element" would "exert an extraneous pull on the scheme established by Congress").

Respondents also note that the FDA's amicus brief "made clear that it agrees with the decision of the New Jersey Supreme Court" on the preemption issue. BIO 16. But that is an issue to be decided by the courts, not the affected agency. While this Court may under some circumstances defer to the FDA's interpretation of its regulations, *see Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2166 (2012), it does not defer to the FDA's legal conclusions about whether federal law preempts state law. As this Court has said in this very context: "Although we defer to the agency's interpretation of its regulations, we do not defer to an agency's ultimate conclusion about whether state law should be preempted." *Mensing*, 564 U.S. at 613 n.3. In *Mensing*, the FDA argued that the claims should not be held

preempted by federal law, *id.* at 616,[1] but this Court did not defer to that position and instead held the claims preempted pursuant to "the statutory scheme established by Congress," *Mensing*, 564 U.S. at 625. Having an independent judicial determination is especially important where, as here, a specific statutory provision reserves exclusive authority to the federal government.

Respondents' reliance on the FDA's preemption position in an amicus brief in a different case is misplaced. After all, the FDA has taken different positions on preemption questions in other cases,[2] and it may do so again.[3]

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[1] *See also* Brief for the United States as Amicus Curiae Supporting Respondents, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (No. 09-993), 2011 WL 741927.

[2] *See, e.g.*, Brief for the United States as Amicus Curiae Supporting Petitioner, *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008) (No. 06-1498), 2007 WL 4218889; Brief for the United States as Amicus Curiae Supporting Petitioner, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768), 2000 WL 1364441.

[3] Respondents quote the amicus brief as arguing that an "expansive reading of *Buckman* … presumably would have barred the duty to warn claims in *Wyeth*." BIO 16. Respondents offer no argument about the supposed conflict with *Wyeth v. Levine*, 555 U.S. 555 (2009), and it is not clear why they think the failure-to-warn claim in *Wyeth* would be treated the same as the failure-to-update claims here, which seek to enforce the FDCA's "federal duty of 'sameness'" that requires a generic label to match that of the RLD. *Mensing*, 564 U.S. at 613. Petitioners' § 337(a) defense was neither raised nor addressed in *Wyeth*: Ms. Levine was not seeking to enforce federal *requirements*, so her case did not implicate *Buckman* or § 337(a). *Wyeth* instead turned on the fact that "the federal regulations ap-

D. This Case Will Not Be Mooted.

Respondents observe that claims at issue in this case may settle but concede that they "cannot represent that, as a result of this settlement agreement, no claims will remain." BIO 17. That concession undermines Respondents' assertion that there is a mootness problem here.

As Petitioners explained to this Court in their letter of January 25, 2017, Petitioners entered into an agreement in principle with attorneys representing individual plaintiffs in the several thousand metoclopramide cases pending nationwide, including lawsuits in the New Jersey Mass Tort Proceeding that is the subject of this action. The settlements with the individual plaintiffs are contingent on a condition precedent that the plaintiffs may not meet, and therefore it is uncertain whether any settlements will occur.

Even so, conversations with counsel representing individual plaintiffs indicate that at least some plaintiffs are expected to opt out of the contemplated settlement and continue litigating their claims. As Respondents concede, all plaintiffs have the option of opting out. BIO 17. This litigation will therefore continue.

This Court has a mechanism for entertaining motions to dismiss as moot or receiving suggestions of mootness. *See* Sup. Ct. R. 21.2(b). It should not allow Respondents effectively to prevail on such a motion

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plicable to Wyeth *allowed* the company, *of its own volition*, to strengthen its label in compliance with its state tort duty." *Mensing*, 564 U.S. at 624 (emphasis added).

before the fact by denying the petition based on Respondents' speculative assertions about possible future conduct under a nonexistent "may largely be mooted" standard.

E. No Prudential Considerations Warrant Denial.

First, Respondents suggest this Court await the development of a record. BIO 18. But no record is necessary here. The only question is whether federal law allows Respondents to proceed on the failure-to-update theory. No factual development is required to address that legal question, which is why the New Jersey Supreme Court granted discretionary review on an interlocutory basis in the first place.

Second, Respondents reference the "narrow scope of the Superior Court's ruling." BIO 18. But the ruling is not narrow. It allows claims to proceed *whenever* there has been a change to the brand-name label, with state juries determining whether the generic matched the change within a reasonable time. *See* App. 74a (Superior Court noting that "reasonableness is usually a jury question" and that "as far as the FDA is concerned you had to change your label immediately. That's what the law says."). The ruling subjects the generic pharmaceutical industry to a potential flood of complaints. The ruling is not limited to "a highly unusual confluence of circumstances," BIO 17, but applies to all cases short of instantaneous label changes.

Third, after insisting that this case does not involve a division of authority at all, Respondents insist that the split is actually *broader* than the ques-

tion presented and that this Court should await a petition that includes "failure-to-communicate" claims as well. BIO 18-19. Failure-to-communicate claims involve impossibility preemption; the question is whether *Mensing* precludes such claims because generic manufacturers cannot disseminate additional communications. *See Morris*, 713 F.3d at 777 (holding that "*Mensing* forecloses such claims because failure to 'communicate' extends beyond just a label change"). By contrast, Petitioners' argument here involves *Buckman*'s prohibition on private enforcement of the FDCA. It is a virtue of the petition that the Court may consider independent issues separately.[4]

Fourth, Respondents note that this Court has denied prior petitions addressing the same circuit split. BIO 19. That means only that this issue frequently recurs and it should finally be resolved by this Court.

CONCLUSION

The petition should be granted.

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[4] Moreover, every circuit court to address failure-to-communicate claims has held those claims preempted. *See Morris*, 713 F.3d at 777; *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 932-33 (6th Cir. 2014); *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139 (8th Cir. 2014); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1288 (10th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013).

Respectfully submitted,

RICHARD A. OETHEIMER
SARAH K. FREDERICK
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000

Counsel for Petitioner Teva Pharmaceuticals USA, Inc.

JOSEPH P. THOMAS
LINDA E. MAICHL
ULMER & BERNE LLP
600 Vine Street
Suite 2800
Cincinnati, OH 45202
(513) 698-5000

Counsel for Petitioner Watson Laboratories, Inc.

JAY P. LEFKOWITZ
Counsel of Record
STEVEN J. MENASHI
ELLIOT C. HARVEY SCHATMEIER
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800

Counsel for Petitioners PLIVA, Inc., Barr Pharmaceuticals, LLC, Barr Laboratories, Inc., Watson Laboratories, Inc., and Teva Pharmaceuticals USA, Inc.

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