No.

IN THE
Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC., BARR PHARMACEUTICALS LLC, BARR LABORATORIES, INC., AND CARACO PHARMACEUTICAL LABORATORIES, 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

PETITION FOR WRIT OF CERTIORARI

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February 7, 2014

QUESTION PRESENTED

Whether the California Court of Appeal erred when it deepened an acknowledged circuit split and held—contrary to this Court's decisions in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); the decisions of the Fifth and Eleventh Circuits in *Morris v. PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013), and *Guarino v. Wyeth, LLC*, 719 F.3d 1245 (11th Cir. 2013); and the plain language of the federal Food, Drug, and Cosmetic Act ("FDCA")—that federal law does not preempt state tort claims predicated on allegations that a generic drug manufacturer violated the FDCA by failing to immediately implement or otherwise disseminate notice of labeling changes that the United States Food and Drug Administration ("FDA") had approved for use on a generic drug product's brand-name equivalent.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, petitioners state as follows:

1. Petitioner Teva Pharmaceuticals USA, Inc. ("Teva USA") is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva Limited"), and is directly owned by (i) Orvet UK (Majority Shareholder), which in turn is directly owned by Teva Pharmaceuticals Europe B.V., which in turn is directly owned by Teva Limited; and (ii) Teva Pharmaceutical Holdings Coöperatieve U.A. (Minority Shareholder), which in turn is directly owned by IVAX LLC, a direct subsidiary of Teva USA. No publicly held company other than Teva Limited directly or indirectly owns 10% or more of the stock of Teva USA.

2. Petitioner Barr Laboratories, Inc. was wholly owned by Barr Pharmaceuticals, Inc. In December 2008, Barr Pharmaceuticals, Inc. was merged into a wholly owned subsidiary of petitioner Teva USA, which as set forth above is an indirect wholly owned subsidiary of Teva Limited. After the merger, the surviving company changed its name to Barr Pharmaceuticals, LLC. No publicly held company other than Teva Limited directly or indirectly owns 10% or more of the stock of the Barr petitioners.

3. Petitioner Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is wholly owned by Sun Pharma Global, Inc. and Sun Pharmaceutical Industries, Ltd. Sun Pharmaceutical Industries, Ltd. is a publicly held company. In February 2013, Caraco merged with Sun Pharmaceutical Industries, Inc. (which also was named in this lawsuit) and as a result of that merger, Caraco is the surviving entity.

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INTRODUCTION

In 2001, this Court held *without dissent* that federal law bars private parties from pursuing state-law tort claims that are predicated on alleged violations of the federal Food, Drug, and Cosmetic Act (the "FDCA"). In the Court's words, the "FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [Act]: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (quoting 21 U.S.C. § 337(a)).

Despite *Buckman*'s clarity, however, the lower courts long have divided over *Buckman*'s scope—and that division has sharpened considerably in recent years, as plaintiffs around the country began advancing novel legal claims designed to evade this Court's preemption holdings in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). The California Court of Appeal's decision in this case frames the nationwide split of authority over *Buckman*'s scope in its sharpest possible relief: The appellate court *expressly* departed from both federal *and* other state appellate decisions which have held that federal law preempts the very same novel tort theory that the appellate court's decision allows plaintiffs to pursue in California. Moreover, courts across the country have continued to divide on the question presented here in the wake of this decision.

Given this open and acknowledged division of authority and its impact on literally thousands of

pending cases that present this same question, we respectfully submit that this Court should definitively resolve the direct conflict among the state and federal appellate courts over the generic industry's exposure to private litigation predicated on allegations that generic drug manufacturers violated federal law.

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Like *Mensing* and *Bartlett*, this case arises from "the special, and different, regulation of generic drugs" under the Hatch-Waxman Amendments to the FDCA ("the Hatch-Waxman Act"). *Mensing*, 131 S. Ct. at 2582. Among other things, that statute provides that when a brand-name drug manufacturer alters its labeling, manufacturers of an FDA-approved generic version of that drug must in most cases replicate the FDA-approved changes in their own product labeling (there is an exception for new language that conveys patent-protected information, but that is not at issue here). This "duty to update" drug labeling is of course a *federal* one; it is exclusively a creature of *federal law* that stems from *the FDCA's* "ongoing *federal duty* of sameness." *Id.* at 2575 (emphasis added).

For obvious reasons, however, there inevitably is some period of delay before generic manufacturers can implement the FDA-mandated changes. Generic manufacturers must first learn that FDA has approved the brand manufacturer's changes. They must draft, prepare, and then produce revised labeling that reflects the changes. They must notify FDA of the intended changes. And in most cases, there is a natural lag before manufacturers are scheduled to ship new batches of product that bear

the revised labels—weeks, months, and in rare cases, years. FDA is well aware of this practical reality, and throughout Hatch-Waxman's nearly thirty-year history, the Agency consistently has exercised its enforcement discretion by declining to target the inevitable gaps that occur between its approval of branded labeling changes and the subsequent implementation of revised labeling by generic drug manufacturers.

Consistent with FDA's federal enforcement decisions, private plaintiffs never previously attempted to premise putative state tort claims on generic manufacturers' alleged (and often fleeting) violation of the FDCA's sameness requirement. Instead, they pursued traditional state law failure-to-warn and design-defect claims against generic manufacturers whose products allegedly caused them injury. But in *Mensing* (and again in *Bartlett*), this Court barred plaintiffs from pursuing those traditional state-law claims, by holding that federal law preempts state-law claims targeting generic drug warnings and designs. *Mensing*, 131 S. Ct. at 2581; *Bartlett*, 133 S. Ct. at 2480.

Even before the ink dried on *Mensing*, plaintiffs around the country began advancing a newly minted theory of liability contrived solely to evade that decision. And today, these so-called "failure-to-update" claims have become the principal line of attack for plaintiffs' lawyers: in literally thousands of cases, plaintiffs now allege that generic companies that did not *instantaneously* update their labeling violated the *federal* sameness requirement and therefore can be held liable under *state* law.

The federal district courts that first considered these "failure-to-update" claims almost universally understood that such claims are a thinly veiled attempt to enforce the FDCA and therefore are preempted under *Buckman* and § 337(a). *See infra* at 21. And when these claims eventually reached the appellate courts, the Fifth Circuit understood that point as well. In *Morris v. PLIVA, Inc.*, that court held that *Buckman* flatly bars putative state-law claims predicated on allegations that a generic maker violated the federal duty of sameness by failing to immediately implement labeling changes: "[A] claim that [a generic manufacturer] breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted." 713 F.3d 774, 777 (5th Cir. 2013) (per curiam) (citing *Buckman*, 531 U.S. at 349 n.4; 21 U.S.C. § 337(a)). The first state appeals court to consider such claims likewise found them preempted. *See Huck v. Trimark Physicians Grp.*, 834 N.W.2d 82 (Iowa Ct. App. 2013), *pet. for review filed*, No. 3-129/12-0596 (Iowa S. Ct. May 14, 2013).

Expressly departing from both *Morris* and *Huck*, the Court of Appeal here chose to follow the Sixth Circuit's circuit-splitting decision in *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013)—allowing plaintiffs in literally hundreds of pending cases to pursue *the same* failure-to-update theory *Morris* and *Huck* rejected, based on *the same* alleged violation of the federal sameness requirement, against *the same* type of defendant (generic drug companies like petitioners) with respect to *the same* type of product (a generic drug approved under the FDCA). In direct conflict with *Morris*'s and *Huck*'s recognition that such failure-to-update claims necessarily hinge on

alleged violations of federal law and thus are preempted, however, the Court of Appeal declared in this case that such claims instead are "based on the alleged failure to properly label alendronate sodium, not to enforce the FDCA or to prevent [petitioners] from violating it." App. 21a. And it reached that conclusion even though the operative complaint candidly acknowledges that these claims in fact hinge entirely on an alleged violation of the FDCA's federal sameness requirement: "As holders of ANDAs for generic versions of the drug, [petitioners] are and have been required *by federal law* . . . to make timely revisions to the labeling." App. 74a (emphasis added); *see also* App. 73a (alleging that "Subsections (a) and (j) of FDCA § 505 … required [petitioners] to include proposed labeling for the drug that is the same in all material respects to the labeling approved" for the branded equivalent).

Since this decision issued, the split of authority on this question only has deepened. Citing this case and *Fulgenzi*, a Pennsylvania appellate court—in a decision that controls *thousands* of plaintiffs' claims—now has embraced such claims. *See In re Reglan/Metoclopramide Litig.*, 81 A.3d 80 (Pa. Super. Ct. 2013).

The nationwide split on this recurring question of federal law is stark, and given that these decisions subject both petitioners and the rest of the generic drug industry to directly conflicting rulings regarding their exposure to personal injury claims, this Court should definitively resolve the conflict.

On the merits, the California Court of Appeal's rule cannot be squared with *Buckman* or § 337(a). As *Buckman* explained, that statute "leaves no

doubt" that the federal government *alone* has authority to "file suit for noncompliance with the [FDCA]." 531 U.S. at 349 n.4 (citing § 337(a)); *id.* at 352 ("Congress intended that the [FDCA] be enforced exclusively by the Federal Government.") (same).

The appellate court tried to evade that holding by asserting that plaintiff's "tort claims under California law parallel the federal safety requirements arising under the FDCA," and thus "do not exist solely due to [petitioners'] alleged failure to comply with those requirements." App. 21a. But that was equally true in *Buckman*, where the plaintiffs filed *state common-law fraud claims* that sought redress for allegedly fraudulent representations that *also* violated the FDCA and allegedly caused the plaintiffs' personal injuries. *Buckman*, 531 U.S. at 346-47. No less than the common-law fraud claim in *Buckman*, the operation of the federal regulatory regime is "a critical element in [this] case." *Id.* at 353. After all, these particular state-law claims arose *only* because FDA approved the brand maker's new labeling, and *only* because of the Hatch-Waxman Act's federal duty of sameness. Indeed, that federal duty of sameness—not any independent state-law duty—circumscribes *both* the subject-matter of this state-law claim *and* its precise content. In short, without the FDCA and the FDA, there could be no claim against petitioners.

Given the parallels between this case and *Buckman*, it is no surprise that the same policy concerns which animated *Buckman* fully apply here. As this Court explained, the FDCA implicates an array of competing policy interests, and § 337(a) reflects Congress's judgment that FDA alone is

capable of balancing those interests in making enforcement decisions. *Buckman*, 531 U.S. at 350-51. Just as FDA has ample authority to address alleged fraud by regulated parties, it has ample authority to address alleged regulatory violations by the parties it regulates and a clear need to calibrate its enforcement activity consistent with administrative policies and priorities. Allowing private plaintiffs to seek compensatory and punitive damages outside of the federal structure necessarily undermines FDA's ability to police the federal scheme in a manner consistent with Agency prerogatives. And allowing such claims to proceed is especially troubling in cases like this one, where plaintiff cannot dispute that petitioners timely submitted the relevant labeling updates to FDA—petitioner Teva, for instance, did so *within weeks* of brand manufacturer's approval—and where FDA thus sensibly declined to take any enforcement action against petitioners.

At bottom, the Court of Appeal's decision is irreconcilable with § 337(a) and *Buckman*, widens an entrenched and expanding split of authority among both the federal and state appellate courts, and implicates significant policy concerns that warrant this Court's review. The petition should be granted.

OPINIONS BELOW

The California Court of Appeal's opinion is reported at 217 Cal. App. 4th 96, and reprinted in the Appendix ("App.") at 1a-28a. The minute order of the Superior Court of California, Orange County, overruling petitioners' demurrer is not officially reported, but is reprinted in the Appendix at 29a-30a. The Superior Court's certification order is not

officially reported, but is reprinted in the Appendix at 31a-32a. The California Supreme Court's denial of the petition for review is not officially reported, but is reprinted in the Appendix at 33a.

JURISDICTION

The Court of Appeal's opinion was filed on June 13, 2013. On July 24, 2013, petitioner filed a timely petition for review, which the California Supreme Court denied on September 25, 2013. App. 33a. On December 3, 2013, the Teva and Barr petitioners timely filed a consent application for an extension of time to file a petition for writ of certiorari until February 7, 2014, which Justice Kennedy granted on December 5, 2013. On December 13, 2013 and December 30, 2013, petitioner Caraco timely filed consent applications for an extension of time to file a petition for writ of certiorari until February 7, 2014, which Justice Kennedy granted on January 8, 2014. This Court has jurisdiction under 28 U.S.C. § 1257(a).

PERTINENT CONSTITUTIONAL AND STATUTORY PROVISIONS

The Supremacy Clause of the U.S. Constitution provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the

> Constitution or Laws of any State to the Contrary notwithstanding.

U.S. CONST. art. VI, cl. 2.

The pertinent provisions of the federal Food, Drug, and Cosmetic Act are set forth in the Appendix, App. 100a-111a.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

From the time of its enactment in 1938—and at all times since—the FDCA has provided in clear, unambiguous terms that (except for certain lawsuits brought by state governments) "*all* … proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a) (emphasis added). In *Buckman*, this Court held that the FDCA's exclusive grant of enforcement authority to the federal government impliedly preempts private lawsuits that are predicated on alleged violations of the statute. "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [statute]: '[A]ll 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 n.4 (quoting 21 U.S.C. § 337(a)).

Among the many FDCA provisions subject to § 337(a)'s prohibition against private enforcement is the Hatch-Waxman Act, which Congress added to the statute in 1984 in order to expand access to affordable generic drugs by reducing barriers to generic market entry. Those amendments gave birth to the modern generic drug industry, and during the

past three decades have reduced pharmaceutical expenditures by literally trillions of dollars. *See Mensing*, 131 S. Ct. at 2582 ("Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public.").

As this Court well knows, the Hatch-Waxman Act achieved its goals because it drew sharp distinctions between branded and generic drug applicants. While brand companies seeking to market an innovative drug product must submit a New Drug Application ("NDA") that includes clinical trial reports demonstrating the proposed product's safety and efficacy, *id.* at 2574 (citing 21 U.S.C. § 355(b)(1), (d)), generic drug companies seeking to market copies of previously approved drugs may file an Abbreviated New Drug Application ("ANDA") that demonstrates the product's chemical and biological equivalence to a previously approved drug (known as the "reference listed drug" or "RLD," which generally is a brand-name drug). *Id.* (citing 21 U.S.C. § 355(j)(2)(A)). To that end, Hatch-Waxman requires ANDA applicants to show that their generic drugs contain *the same* active ingredients, employ *the same* route of administration (*e.g.*, oral or injected), present *the same* dosage form, exhibit *the same* strength, and thus "have *the same* therapeutic effect" as the branded equivalent to which their ANDA refers. 21 U.S.C. § 355(j)(2)(A)(i)-(iv) (emphasis added).

Because "sameness" is the touchstone for generic approval, federal law provides that generic labeling—including its warnings and other safety-related information—must in all pertinent respects be "the same as the labeling approved for the [brand-

name] drug." *Mensing*, 131 S. Ct. at 2574 (quotations and citation omitted, alteration in original). As *Mensing* thus explained:

> [B]rand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's.

Id. at 2574 (citations omitted).

These distinctions between brand and generic responsibilities extend to labeling updates after approval. While NDA holders may in certain circumstances revise their labeling unilaterally (*i.e.*, without prior FDA approval) to "add or strengthen a contraindication, warning[,] precaution" or adverse reaction through the "changes being effected" (or "CBE") procedure, *Mensing*, 131 S. Ct. at 2575 (discussing 21 C.F.R. § 314.70(c)(6)), ANDA applicants may not. Instead, ANDA applicants may use the CBE regulation to make "changes to generic drug labels *only* when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." *Id*. (emphasis added).[1]

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[1] FDA recently proposed to amend the CBE regulation to permit generic drug companies to unilaterally revise their product labeling in certain circumstances. *See Supplemental*

Even so, neither the FDCA nor FDA's implementing regulations require generic manufacturers to implement labeling changes within a specified period of time (*e.g.*, within 60, 90 or 120 days). Instead, FDA has advised the industry that it would "notify ANDA applicants by facsimile, telephone, and/or letter for any labeling revision approved for the RLD that warrants immediate widespread professional notification, such as those changes connected to issuing a Dear Doctor Letter or similar significant changes." FDA, Center for Drug Evaluation and Research, Office of Generic Drugs, *Guidance for Industry: Revising ANDA Labeling Following Revision of the RLD Labeling*, at 2 (May 2000) (emphasis omitted). Outside those circumstances, however, the Agency historically has exercised its enforcement discretion with respect to the timing of generic labeling updates on a case-by-case basis.

B. Proceedings Below

Petitioners manufacture generic drugs, one of which is alendronate sodium—a generic equivalent to Merck Sharp & Dohme Corp.'s ("Merck's") osteoporosis treatment Fosamax®. In April 2011, nearly 200 product-liability suits targeting Fosamax® and alendronate sodium products were coordinated for pretrial proceedings in the Orange County, California Superior Court. App. 4a. After

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Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985 (Nov. 13, 2013). The comment period on the proposed rule remains open, and even if adopted, the rule would have no impact on this case—or the thousands of pending cases just like it—which seeks to impose liability for past violations of the FDCA.

this Court held in *Mensing* that Hatch-Waxman preempts traditional state-law claims targeting generic drug warnings, the parties agreed that plaintiffs would file a "test case" complaint designed to "raise and resolve the issue of federal preemption." *Id.*

In that complaint, plaintiff Olga Pikerie asserted eleven causes of action against both the brand-name and generic manufacturers who allegedly produced the alendronate products she consumed.[2] In an attempt to evade *Mensing*'s preemption holding, plaintiff contended that when she ingested alendronate sodium in 2010 and 2011, the labeling on the generic products she consumed was not identical to the labeling for Fosamax®. App. 73a-74a. Specifically, plaintiff alleged that (i) in March 2010, FDA approved a change to Merck's labeling to include a "reference, although not a warning, to 'low-energy femoral shaft and subtrochanteric fractures;" and (ii) in January 2011, FDA approved a change in the precautions section of the labeling which provided additional detail regarding the risks of "[a]typical, low-energy or low-trauma fractures of the femoral shaft." App. 57a-58a. According to the

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[2] In addition to petitioners, Northstar Rx LLC ("Northstar") and Mylan Pharmaceuticals, Inc. ("Mylan") participated in the underlying appellate proceedings. Because Northstar was dismissed after the California Court of Appeal issued the decision at issue here, and because Mylan was "not named as a defendant in Pikerie's complaint," App. 5a n.1, neither Northstar nor Mylan is a petitioner here. Finally, while McKesson Corporation ("McKesson") was named as a defendant in the complaint, it was never served, and therefore McKesson neither participated in any proceedings with respect to this case before the California courts nor is a petitioner here.

complaint, petitioners were "required *by federal law* … to make timely revisions to the labeling … after revisions were made to the RLD label," App. 73a-74a (emphasis added), but allegedly failed to do so immediately and thereby caused plaintiff's alleged injuries. App. 79a.[3]

Although plaintiff put various state-law *captions* on her claims, their *substance* made clear that she in reality sought to enforce petitioners' federal duty to update their labeling under the FDCA. In plaintiff's words:

> 119. *Per the provisions and procedures established under Subsections (a) and (j) of FDCA § 505, as amended by the Hatch-Waxman Amendments*, an ANDA for a generic version of Alendronate Sodium *has been required* to include proposed labeling for the drug that is the same in all material respects to the labeling approved for the so-called Reference Listed Drug (RLD), which was Fosamax.
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> ***
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> 121. As holders of ANDAs for generic versions of the drug, GENERIC DEFENDANTS *are and have been*

[3] Discovery in other pending alendronate litigation has shown that petitioner Teva, for instance, submitted its alendronate labeling changes to FDA on April 12, 2010 and March 8, 2011, respectively—about six weeks after FDA approved the two branded product labeling changes cited in plaintiff's complaint.

> *required by federal law* … to make timely revisions to the labeling of the labels [*sic*] for their Alendronate Sodium products after revisions were made to the RLD label.
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> ***
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> 126. GENERIC DEFENDANTS failed to timely and properly correct misstatements and misrepresentations in the label, *failed to update the label*, failed to ensure that the true risk of femoral fracture were [*sic*] accurately stated in the label, and *failed to utilize FDA approved means* to properly emphasize and reinforce the warnings about the duration of use of the PRODUCTS.

App. 73a, 74a, 79a (emphases added).

On January 31, 2012, petitioners filed a demurrer asserting that plaintiff's claims were preempted. Plaintiff responded by asserting that her state-law claims survived preemption because *federal law* obligated petitioners to update their labeling so that it matched the brand manufacturer's labeling. Relatedly, plaintiff asserted that petitioners could be held liable because they at least could have sent a Dear Doctor Letter or similar correspondence altering physicians to the new warnings

On May 5, 2012, the trial court issued a two-page minute order overruling the demurrer, on the grounds that "[t]he complaint alleges at least 2 areas of conduct which appear not to be preempted --

failure to timely make FDA labeling changes and a duty to communicate beyond the labeling and failure to do so. These facts are sufficient to constitute causes of action which are not preempted." App. 30a (internal references omitted). On June 29, 2012, the trial court entered an order under California Code of Civil Procedure section 166.1 certifying for immediate appellate review the question whether federal law preempts plaintiff's claims, on the ground that this issue is "a controlling question of law … as to which there are substantial grounds for difference of opinion." App. 32a.

On July 9, 2012, petitioners and their generic co-defendants timely filed a petition for writ of mandate in the California Court of Appeal, arguing (*inter alia*) that the trial court's holding conflicted with both *Mensing* and *Buckman*. The Court of Appeal thereafter issued an order to show cause why the writ should not issue. Order (10/23/12), at 1. Plaintiff reiterated the same defense of her claims that she had advanced in the trial court, but openly conceded that the failure-to-update theory "is the basis for each of [her] state-law claims" and emphasized that petitioners' alleged "violation of a federal regulation … form[s the] basis for a negligence claim under a negligence *per se* evidentiary standard." Plf's Ans. Br. at 27 (Cal. Ct. App., filed Dec. 7, 2012); *see also* Plf's Ans. Br., 2013 WL 4787272, at *7 (Cal. S. Ct., filed Aug. 14, 2013) (same).

On June 13, 2013, the Court of Appeal issued an opinion denying the petition on the merits. The panel first rejected petitioners' argument that plaintiff's failure-to-update claim is preempted. It

began by holding that *Buckman* is narrowly limited to claims that assert fraud on the FDA: "[Plaintiff's] claims are not based on a fraud-on-the-FDA theory, but on state law tort principles of a drug manufacturer's duty to the consumers of its product." App. 20a. The appellate court acknowledged that the text of 21 U.S.C. § 337(a) includes no such limitation, but asserted that plaintiff's claims are not subject to the law's prohibition on private enforcement because they "are … based on the alleged failure to properly label alendronate sodium, not to enforce the FDCA or to prevent [petitioners] from violating it," App. 21a—even though the complaint itself repeatedly alleged that petitioners were liable precisely because they violated *the federal sameness requirement*. Along the way, the Court of Appeal expressly rejected the Fifth Circuit's decision in *Morris* and the Iowa Court of Appeal's decision in *Huck*. App. 18a-19a & n.3, 21a n.4.

Finally, the panel held that the plaintiff's so-called "failure-to-communicate" claim—which asserts that generic manufacturers may unilaterally send "Dear Doctor" letters to healthcare providers warning of their products' risks—could proceed, despite *Mensing*'s specific holding that generic defendants cannot send such letters unless the brand-name manufacturer does so first: "[I]f generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly misleading." *Mensing*, 131 S. Ct. at 2576 (citation and internal quotation marks omitted); *see also Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013) ("Guarino's attempt to

elude *Mensing* by clothing her allegations as 'failure-to-communicate' claims rather than failure-to-warn claims does not alter our analysis. No matter the garb in which she attempts to present them, Guarino's claims are at bottom allegations regarding [petitioners'] failure to warn …, and they therefore cannot escape *Mensing*'s grasp."); *Morris*, 713 F.3d at 777 ("Under federal law, the inquiry is whether the brand-name manufacturers sent out a warning," and "[b]ecause no brand-name manufacturer sent a warning …, the generic manufacturers were not at liberty to do so.").

Petitioners filed a timely petition for review in the Supreme Court of California. But with three of the court's seven Justices recused due to apparent conflicts, the petition was denied on September 25, 2013. This petition follows.

REASON FOR GRANTING THE WRIT

The Appellate Court Erred When It Deepened An Acknowledged Circuit Split And Held That Federal Law Does Not Preempt State Tort Claims Predicated On Allegations That A Generic Drug Maker Violated The FDCA By Failing To Immediately Implement Or Otherwise Disseminate Notice Of Labeling Changes That FDA Had Approved For Use On A Generic Drug's Brand-Name Equivalent.

This case presents the question whether federal law preempts putative state personal-injury claims that are predicated on a generic drug manufacturer's alleged failure to promptly update and otherwise disseminate revised labeling in alleged violation of the FDCA. That issue now has been briefed and argued to multiple federal and state appellate courts,

and those courts are deeply and irreconcilably divided on the answer. The resulting split affects countless litigants, including scores of generic drug manufacturers and literally thousands of plaintiffs seeking to pursue such claims. And it subjects petitioners and other generic drug manufacturers to directly conflicting liability rules depending on the jurisdiction in which they happen to be sued. Only this Court can definitively resolve the split over this important question of federal law, and this case provides an excellent vehicle for the Court to do so.

As set forth above, the operative complaint in this case alleges that petitioners were "required *by federal law* … to make timely revisions to the labeling of their [products]," App. 73a-74a (emphasis added); that petitioners "breached their duty … under Subsections (a) and (j) of FDCA § 505, as amended by the Hatch-Waxman Amendments" by failing to update their labeling quickly enough, App. 79a, 73a; and that plaintiff was injured as a result. App. 80a. Even though these claims thus explicitly seek to enforce federal law, the appellate court joined the Sixth Circuit's decision in *Fulgenzi* by holding that *Buckman* and § 337(a) do not preempt such failure-to-update claims.

That holding directly conflicts with the decisions of the Fifth Circuit in *Morris* and the Iowa Court of Appeal in *Huck*, and there is no material difference between these cases. As here, the *Morris* and *Huck* plaintiffs allegedly consumed a generic drug, were injured as a result, and then sued the generic manufacturer under various state product liability theories. *Morris*, 714 F.3d at 775-76; *Huck*, 834 N.W.2d at *1. And as here, the *Morris* and *Huck*

plaintiffs responded to *Mensing* by asserting that the generic manufacturer-defendant in those cases could be held liable because it failed to update its warnings "to comply with [an] FDA-approved label change" to the branded product in those cases. *Morris*, 713 F.3d at 776; *Huck*, 834 N.W.2d at *3 (describing plaintiff's claim as asserting that the generic defendant "is liable to [plaintiff] because it failed to update its label to conform with the" branded labeling).

Indeed, the *only* difference between this case and those cases is that the other courts correctly recognized that federal law bars private plaintiffs from pursuing claims predicated on a generic manufacturer's alleged violation of Hatch-Waxman's federal duty of sameness. As *Morris* explained, any "claim that [a generic manufacturer] breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted." *Morris*, 713 F.3d at 777 (citing 21 U.S.C. § 337(a) and *Buckman*); *see also Huck*, 834 N.W.2d at *3 (holding plaintiff's failure-to-update theory preempted because "[t]he requirement for generic drug labeling to be the same as the [branded] label arises under federal law, which explicitly prohibits private attempts to enforce the Food Drug and Cosmetic Act (FDCA)") (citing 21 U.S.C. § 337(a)). Not surprisingly, this split continues to deepen: Following this decision, a divided Pennsylvania appellate court likewise held—in a case involving the coordinated claims of over 2,000 plaintiffs—that federal law does not preempt the same theory at issue here. *See In re Reglan/Metoclopramide Litig.*, 81 A.3d at 96.

The federal district courts likewise are divided on this question and have reached directly conflicting results in materially indistinguishable cases. The majority of courts side with the Fifth Circuit and the Iowa Court of Appeal and have dismissed failure-to-update claims. *See, e.g.*, *Abicht v. PLIVA, Inc.*, Nos. 12-1278, 12-2172, 2013 WL 141724, at *2, 3 (D. Minn. Jan. 9, 2013); *Brinkley v. Pfizer, Inc.*, No. 10-0274-CV-W-SOW, 2012 WL 1564945, at *5 (W.D. Mo. Apr. 12, 2012); *Bell v. PLIVA, Inc.*, 845 F. Supp. 2d 967, 970 (E.D. Ark. 2012), *aff'd in relevant part on other grounds sub nom. Bell v. Pfizer, Inc.*, 716 F.3d 1087 (8th Cir. 2013); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 2:11-MD-2226-DCR, 2012 WL 718618, at *4 n.8 (E.D. Ky. Mar. 5, 2012); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 660 (D. Md. 2011). At the same time, several district courts have sided with the appellate court in this case and the Sixth Circuit, by permitting similar claims to proceed. *See, e.g.*, *In re Fosamax Prods. Liab. Litig.*, __ F. Supp. 2d __, 2013 WL 4306434, at *3-4 (S.D.N.Y. Aug., 15, 2013); *Neeley v. Wolters Kluwer Health, Inc.*, 2013 WL 3929059, at *8-9 (E.D. Mo. July 29, 2013); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1065-66 (D. Or. 2013); *Lyman v. Pfizer, Inc.*, 2012 WL 2970627, at *9-11 (D. Vt. July 20, 2012); *Couick v. Wyeth, Inc.*, 2012 WL 79670, at *5 (W.D.N.C. Jan. 11, 2012); *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 834 (D.S.C. 2011).

Unless and until this Court provides clarity, however, this entrenched nationwide division in authority threatens to subject thousands of similarly situated parties to irreconcilable rulings in cases involving scores of different drug products. The problem will only grow as decisions like the one here

lead plaintiff's lawyers to file suit every time the FDA's website reveals a labeling change that generic companies cannot possibly implement instantaneously. And with the widespread adoption of plaintiff-oriented mass proceedings in various state courts—in California, New Jersey, and Pennsylvania, out-of-state residents have filed and will continue to file product-liability cases against drug manufacturers regardless of where they consumed a defendant's drug product, and literally *thousands* of failure-to-update claims now have been consolidated for pretrial decisions in these three states—the opportunities for forum-shopping in the face of this split are boundless: Texas residents whose claims would be barred under *Morris*, for instance, need only send their complaints to the welcoming courts of California or Pennsylvania, which have allowed the very claims *Morris* found preempted.[4] From the perspective of companies like petitioners, who manufacture or market federally approved products for sale to consumers in all 50 states, it thus is hard to overstate the importance of resolving this nationwide split *now*.

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[4] In the wake of certain rule changes in Philadelphia's Center for Complex Litigation, for instance, the administrative judge responsible for the court's civil trial division recently sought to reassure the national plaintiffs' bar that Philadelphia remains "plaintiff-friendly." P.J. D'Annunzio, *"Lull" Seen By Attorneys In Phila.-Based Mass Tort Litigation*, THE LEGAL INTELLIGENCER, Nov. 5, 2013. "Ever since I wrote the protocols there has been some concern from out-of-state lawyers that Philadelphia is not a friendly forum. That is not the attitude of Pennsylvania lawyers, who actually helped write the protocols." *Id*. (quoting interview).

Should this Court grant review, the appellate court's decision should be reversed for the same reasons *Buckman* rejected state-law fraud claims predicated on allegations that a regulated party violated its federal duties under the FDCA. Indeed, these cases are virtually indistinguishable. Both here and in *Buckman*, plaintiffs filed putative state tort claims predicated on allegations that a defendant's violation of the FDCA caused the plaintiff to suffer personal injuries. And in both cases, the plaintiffs nominally sought to recover compensatory and punitive damages for those personal injuries under state law—in *Buckman*, asserting common-law fraud based on allegedly false statements that allegedly led to the plaintiffs' injuries; here, asserting state products-liability claims based on petitioners' alleged failure to implement or otherwise disseminate FDA-required labeling changes, which likewise allegedly injured plaintiff.

Despite the avowed state-law basis for the plaintiffs' common-law fraud claims in *Buckman*, however, this Court held that those claims necessarily and impermissibly hinged on the antecedent federal scheme: "[T]he very subject matter of petitioner's statements w[as] dictated by [the FDCA's] provisions," *Buckman*, 531 U.S. at 347-48, so allowing claims predicated on alleged violations of the FDCA in connection with those statements would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. Moreover, as *Buckman* observed, FDA's exclusive purview over the alleged violation stemmed directly from the plain language of § 337(a): "The

FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA]: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Buckman*, 531 U.S. at 349 n.4 (quoting 21 U.S.C. § 337(a)); *id.* at 352 ("Congress intended that the [FDCA] be enforced exclusively by the Federal Government.") (citing 21 U.S.C. § 337(a)).

The Court of Appeal nonetheless tried to evade *Buckman* and § 337(a) by asserting that "it was possible for [petitioners] to comply with both a federal duty to makes [*sic*] their labels match the Fosamax label, and a state tort law duty to prevent harm to the consumers of alendronate sodium." App. 15a. But that assertion misses the point. Just as the FDCA "dictated … the very subject matter of petitioner's statements" in *Buckman* and thus necessarily presented a federal issue subject to exclusive federal oversight, 531 U.S. at 347-48, the FDCA's federal duty of sameness in this case "dictated … the very subject matter" *and indeed the precise content* of the warnings petitioners were obligated to provide with their generic alendronate sodium products.

In short, but-for the changes to the branded drug's labeling; but-for FDA's decision to approve those changes; and but-for the Hatch-Waxman Act's federal duty of sameness, plaintiffs would have no basis for seeking to hold petitioners liable for failing to implement the brand manufacturer's changes. That, of course, is why plaintiff's complaint is replete with allegations that petitioners violated their

federal duty of sameness arising "under Subsection (a) and (j) of FDCA § 505, as amended by the Hatch-Waxman Act." *See, e.g.*, App. 73a, 74a, 79a (emphasis added). Those allegations demonstrate in spades that the claims at issue here are the very kind of thinly disguised attempts to enforce federal law that *Buckman* and § 337(a) prohibit.

Indeed, plaintiff's appellate briefing in the state courts removes any doubt on this score. In both the appellate court and the state Supreme Court, plaintiffs stressed that petitioners' purported "violation of a federal regulation … form[s the] basis for a negligence claim under a negligence *per se* evidentiary standard." Plf's Ans. Br. at 27 (Cal. Ct. App., filed Dec. 7, 2012); Plf's Ans. Br., 2013 WL 4787272, at *7 (Cal. S. Ct., filed Aug. 14, 2013) (same). Such claims necessarily (and by design) hinge on the underlying federal violation rather than on some duty that sounds in state law alone; the act giving rise to plaintiff's negligence *per se* claim *is the asserted violation of federal law*, which by definition makes federal law the "critical element in [this] case." *Buckman*, 341 U.S. at 353.

That is why other courts routinely hold that *Buckman* and § 337(a) expressly bar private plaintiffs from pursuing negligence *per se* claims predicated on asserted violations of the FDCA. *See, e.g.*, *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205-06 (8th Cir. 2010) (holding negligence claim premised on failure to comply with FDCA preempted under § 337(a) and *Buckman*); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005) (holding negligence *per se* claim premised on "failing to comply with the FDA's

conditions of approval" preempted under *Buckman*); *Ramirez v. Medtronic Inc.*, __ F. Supp. 2d __, 2013 WL 4446913, at *18-19 (D. Ariz. Aug. 21, 2013) ("[A] claim for negligence that is premised solely on a manufacturer's violation of a federal standard—here the FDCA and MDA—is impliedly preempted. This type of claim presents the exact difficulties that produced implied preemption in *Buckman*."); *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1151-52 (D. Minn. 2011) ("A negligence-per-se claim that is predicated on an alleged violation of the FDCA is, by definition, a claim that would give rise to liability under [state] law only because of the FDCA's enactment. Such a claim is preempted under *Buckman*."); *Leonard v. Medtronic, Inc.*, 2011 WL 3652311, at *8 (N.D. Ga. Aug. 19, 2011) ("[P]laintiffs' claim of negligence per se would not exist prior to the enactment of the FDCA misbranding and adulteration laws because the claim only alleges violation of that law.").

The Court of Appeal nonetheless claimed that plaintiff's failure-to-update claim does not seek "to enforce the FDCA or to prevent [petitioners] from violating it," but is "instead based on the alleged failure to properly label alendronate sodium." App. 21a. Even if that assertion were true (in reality, it is impossible to square with either the complaint's repeated allegations that petitioners violated the duty of sameness "required by *federal law*" or plaintiffs' own description of their claims), it does nothing to reconcile this case with *Buckman*. There as well the plaintiffs sought to pursue a *state common-law claim* for fraud based on actionable false statements and omissions that state law independently prohibited; they did not purport to file

suit under the FDCA itself. 531 U.S. at 346-47; *see also In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 822 (3d Cir. 1998) ("Count I is thus drafted to track the elements of a common law cause of action for fraudulent misrepresentation: (1) a representation of fact, opinion, intention or law; (2) knowledge of its falsity; (3) an intent to induce reliance; (4) justifiable reliance; and (5) resulting injury.") (citing *Restatement (Second) of Torts* § 525 *et seq.* (1977)); *id.* at 826-27 (noting that the plaintiffs' claims in *Buckman* tracked well-known common-law fraud and causation principles reflected in *Restatement (Second) of Torts* § 310 (1965)).

Confronted with that reality, the appellate court eventually declared that *Buckman* is a one-off decision that somehow can be limited to "fraud-on-the-FDA" claims. App. 19a-20a ("Pikerie's claims are based on her contention that the alendronate sodium labels were not complete and accurate, and did not match the warnings on the Fosamax labels, not that [petitioners] committed a fraud on the FDA when submitting their ANDA's [*sic*]."). But there is no principled basis for drawing that line. *Buckman*, after all, relied heavily on § 337(a)—which is not textually limited to state-law claims predicated on alleged fraud-on-the-FDA. Instead, it bars *any* private lawsuit based on alleged noncompliance with the FDCA *as a whole*. 21 U.S.C. § 337(a) ("[*A*]*ll* such proceedings for the enforcement, or to restrain violations, *of this chapter* shall be by and in the name of the United States.") (emphasis added).

As a result, numerous courts have applied *Buckman*'s interpretation of § 337(a) to cases far outside the fraud-on-the-FDA context. *See, e.g.*, *Ellis*

v. C.R. Bard, Inc., 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) (negligence claim); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788-89 (3d Cir. 1999) (conspiracy to market medical devices without FDA approval); *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 797 (N.D. Ohio 2012) ("[A] private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA.") (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).[5]

Against this weight of authority, the appellate court ultimately declared that there is "a principled difference between a federal agency acting in the face of someone trying to defraud it, on the one hand, and a claim by a consumer that a label on a generic drug did not match the FDA-approved RLD label, on the other." App. 20a. Yet it made no effort to identify that "principled difference" or reconcile its *ad hoc* line-drawing with the unqualified language of *Buckman* and § 337(a). And there is no way to do so.

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[5] The Court of Appeal's reliance on *Buckman*'s distinction of *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), to defend its narrow view of *Buckman* is wholly misplaced. As *Buckman* explained, *Silkwood* was inapposite not because it involved something other than a "fraud-on-the-FDA" claim, but because it "turned on specific statutory evidence that Congress 'disclaimed any interest in promoting the development and utilization of atomic energy by means that fail to provide adequate remedies for those who are injured by exposure to hazardous nuclear materials.' In the present case [and here, in *this* case], by contrast, we have clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government. 21 U.S.C. § 337(a)." *Buckman*, 531 U.S. at 352 (quoting *Silkwood*, 464 U.S. at 257).

Whether a manufacturer is alleged to have made false claims in violation of the FDCA or failed to update its labeling in violation of the FDCA, both claims directly implicate the enforcement authority Congress vested exclusively in FDA—and both claims undermine the very "flexibility" *Buckman* recognized as being "a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." 531 U.S. at 349.

As *Buckman* observed, § 337(a) not only vests exclusive authority to police the federal regulatory regime in FDA but places "at [FDA's] disposal a variety of enforcement options that allow it to make a measured response to suspected" violations of the statute and the Agency's implementing regulations. 531 U.S. at 349. In addition to injunctive relief, 21 U.S.C. § 332, FDA can seize misbranded products, *id.* § 334, and it is empowered to pursue both civil penalties and even criminal sanctions against manufacturers that it determines have violated the FDCA *as a whole—not* just its anti-fraud provisions. *Id.* § 333. But as the federal government forcefully argued in *Buckman*—and this Court in turn recognized, 531 U.S. at 348-51—private litigation predicated on alleged violations of the FDCA impermissibly undermines FDA's broad enforcement discretion because it:

> (1) "permit[s] juries in different States to reach judgments that differ from FDA's" about whether companies violated federal law, and potentially "impose massive liability, when FDA would not find any misconduct";

> (2) "distort[s] the penalty scheme established by the statute," by providing remedies Congress withheld (like possible punitive damages); and
>
> (3) "interfere[s] with FDA's discretion to decide which of the statutorily prescribed remedies, if any, to pursue," by allowing juries to "substitute their judgments for FDA's as to the appropriate sanction."

Br. for the United States As Amicus Curiae in Support of Petitioner, *Buckman* (No. 98-1768), 2000 WL 1364441, at *23-*24 (quotations omitted; citing *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 380 (2000); *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)).

Those consequences are on full display here. As noted above, FDA consistently has exercised its enforcement discretion to refrain from targeting the inevitable delays between its approval of revised brand product labeling and the distribution of new labeling by generic companies. Nonetheless, literally thousands of cases premised on delays in updating generic drug labeling—many seeking not only compensatory damages but punitive damages as well—are now pending in state and federal courts across the country.

If those cases proceed to trial, it is inevitable that juries will reach divergent conclusions. Some state-law juries are likely to conclude that even a single day's delay in implementing updated labeling was too long; others are likely to determine that in various circumstances even a years-long delay was entirely defensible. Scores of cases will involve

circumstances where FDA affirmatively determined that a given generic manufacturer's warnings were timely updated under the FDCA, but a jury disagrees. And in others, juries will issue verdicts calling for massive damage awards—including possible punitive damages—where FDA has determined that no sanction is appropriate. Suffice it to say, allowing claims predicated on these alleged violations of the FDCA thus threatens to "skew" FDA's "delicate balance of statutory objectives," 531 U.S. at 348, no less than the common-law fraud claims at issue in *Buckman* threatened to undermine the enforcement "flexibility" that Congress granted FDA to "pursue[] difficult (and often competing) objectives." *Id.* at 349.

Those considerations have particular force in this case. As noted above, petitioner Teva, for example, submitted both of the labeling changes at issue here to FDA *within six weeks* of the dates the Agency approved the corresponding changes to the branded product labeling, and FDA quite sensibly has abstained from sanctioning petitioners for such eminently reasonable conduct. There is thus no basis allowing a lay jury to second-guess FDA's exercise of enforcement discretion by independently assessing the reasonableness of petitioners' actions—under undefined, *ad hoc* state-law standards—and imposing potentially massive liability when faced with a sympathetic plaintiff. Doing so would usurp the balance Congress sought to achieve by placing enforcement discretion in FDA's hands (and FDA's hands *alone*). *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985) ("The [FDCA's] enforcement provisions thus commit complete discretion to the Secretary to decide how and when they should be exercised.")

Given these concerns, the appellate court ultimately embraced plaintiffs' fall-back position: that even if petitioners' alleged violation of the FDCA were not itself actionable under the guise of a state-law claim, petitioners' failure to otherwise disseminate the updated labeling through a Dear Doctor Letter to healthcare providers could be pursued under state law. App. xxx (slip op. xxx).

That claim runs headlong into *Mensing*, where the plaintiffs likewise argued that the generic manufacturer-defendants could have sent a Dear Doctor letter about product risks—and this Court squarely rejected that claim: "[I]f generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" 131 S. Ct. at 2576.

The appellate court nonetheless tried to limit *Mensing* to circumstances where a given Dear Doctor letter would provide new warning information to healthcare providers instead of merely replicating the warnings already provided in the approved labeling: "*Mensing* does not preempt a claim that a generic drug manufacturer failed to send a Dear Doctor letter containing the same information that is on the RLD's approved label." App. 27a. But that assertion ignores both the record in *Mensing* and its procedural posture. That case was decided on a motion to dismiss where the plaintiffs had *never* proffered the proposed text of the Dear Doctor letter they said the defendants should have sent. Indeed, plaintiffs insisted that they could have crafted a Dear Doctor letter that would survive federal

preemption and forcefully asserted that it would be improper to foreclose them from attempting to do so at the motion-to-dismiss stage: "Especially at the motion to dismiss stage, the Court must assume that the Defendants could have drafted a letter that would not have implied any such therapeutic difference [between the branded and generic versions of the drug]." Br. of Respondents, *Mensing*, at 37. This Court, however, rejected their claim anyway—making clear that it was impossible for plaintiffs to craft a letter that did not run afoul of federal law.

That is why both the Fifth Circuit in *Morris* and the Eleventh Circuit in *Guarino* since have rejected the very same argument accepted by the California appellate court in this case. *Morris*, 713 F.3d at 777 ("Because the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead."); *Guarino*, 719 F.3d at 1249 ("We embrace the Fifth Circuit's reasoning and similarly reject the failure-to-communicate theory of liability, as it is preempted by federal law.") (citing *Morris*, 713 F.3d at 777 (explaining that "[u]nder federal law, the inquiry is whether the brand-name manufacturers sent out a warning," and holding that "[b]ecause no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers were not at liberty to do so")).

At bottom, the California court's explicit rejection of these holdings, App. 27a, only underscores the need for this Court to review this issue—and to definitively reject the novel theories now being used to write *Mensing* out of existence.

CONCLUSION

For the foregoing reasons, the Court should grant this petition and reverse the judgment.

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