No. 13-956

In the Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC., ET AL.,
PETITIONERS

v.

SUPERIOR COURT OF CALIFORNIA, ORANGE COUNTY,
ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE COURT OF APPEAL OF CALIFORNIA, FOURTH APPELLATE DISTRICT, DIVISION THREE

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

The Food and Drug Administration approves two types of applications for new drugs under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*: a new drug application for brand-name drugs, and an abbreviated new drug application for generic versions of brand-name drugs. 21 U.S.C. 355(a), (b) and (j). A generic drug's "labeling" must, with exceptions not relevant here, be "consistent with that for the listed [brand-name] drug," 21 C.F.R. 314.150(b)(10). Petitioners are manufacturers of generic versions of a brand-name drug the labeling of which was updated to reflect new safety-related information. Respondent alleges that petitioners breached their state-law duty to warn about their drugs' risks and caused respondent's injury by failing to update their generic-drug labeling promptly and otherwise to communicate the labeling change to healthcare providers. The questions presented are:

1. Whether a drug manufacturer's state-law duty to warn of its generic drug's risks, which is consistent with the federal regulatory obligation to update the generic drug's labeling to match that of its brand-name counterpart, is preempted by 21 U.S.C. 337(a)'s grant of exclusive authority to the United States to enforce, and to restrain violations of, the FDCA.

2. Whether the FDCA renders it impossible to comply with, and thus impliedly preempts, a generic drug manufacturer's state tort-law duty to warn by communicating such updates to healthcare professionals using Dear Health Care Provider letters.

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This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. a. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, authorizes the Food and Drug Administration (FDA) to approve two types of applications for new drugs for marketing in the United States: a new drug application (NDA) for brand-name drugs, and an abbreviated new drug application (ANDA) for generic versions of brand-name drugs. 21 U.S.C. 355(a), (b) and (j). The labeling for both types of drugs plays an important role in

the regulatory framework. See 21 U.S.C. 321(m) (defining "labeling").

First, with respect to brand-name drugs, FDA may approve an NDA only if it determines, *inter alia*, that (i) the drug is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," and (ii) "substantial evidence" shows that "the drug will have the effect it purports or is represented to have" under the conditions of use in the "proposed labeling." 21 U.S.C. 355(d). A drug manufacturer's NDA must therefore include "the labeling proposed to be used for such drug," 21 U.S.C. 355(b)(1)(F), and "a discussion of why the benefits exceed the risks under the conditions stated in the labeling," 21 C.F.R. 314.50(d)(5)(viii).

After FDA approves an NDA and has officially listed the brand-name drug (see 21 U.S.C. 355(j)(7)), and subject to certain periods of exclusivity (see 21 U.S.C. 355(j)(5)(F)), any manufacturer may seek approval to market a generic version of the brand-name drug under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Amendments. Those Amendments prescribe the process for submitting an ANDA for a generic drug based on a previously approved reference listed drug (RLD). 21 U.S.C. 355(j). Unlike the NDA process, the ANDA process does not require independent evidence of a generic drug's safety or efficacy. Instead, an ANDA applicant must generally show that the generic drug is equivalent in relevant respects to the relevant brand-name drug (*i.e.*, the RLD). *Mutual Pharm. Co.* v. *Bartlett*, 133 S. Ct. 2466, 2471 (2013). The applicant must also show that the "labeling proposed for the

new [generic] drug is the same as the labeling approved for the [approved brand-name] drug." 21 U.S.C. 355(j)(2)(A)(v).

b. The labeling for a drug must, *inter alia*, bear "adequate directions for use" under which a lay person could appropriately use the drug, unless FDA has exempted the drug from that requirement. 21 U.S.C. 352(f); 21 C.F.R. 201.5; cf. 21 U.S.C. 331(a)-(c) and (g) (prohibiting misbranded drugs). FDA has exempted prescription drugs, which may be used only under a medical professional's supervision (21 U.S.C. 353(b)), that meet certain conditions. 21 C.F.R. 201.100. That exemption requires, *inter alia*, that a prescription drug's labeling provide information adequate for licensed medical professionals to administer the drug safely for its intended purposes; that such labeling be "the same in language and emphasis as labeling approved or permitted, under the provisions of [21 U.S.C. 355]"; and that any other labeling be "consistent with and not contrary to such approved or permitted labeling." 21 C.F.R. 201.100(d)(1).

A "[drug] manufacturer bears responsibility for the content of its label at all times" and has an ongoing obligation under the FDCA to "ensur[e] that its warnings remain adequate as long as the drug is on the market." *Wyeth* v. *Levine*, 555 U.S. 555, 570-571 (2009). Under FDA's regulations, a manufacturer ordinarily must submit a supplemental NDA or ANDA and obtain FDA's approval for that supplement before making any changes to the approved drug product, including changes to its FDA-approved labeling. 21 C.F.R. 314.70(b)(2)(v), 314.97. FDA's changes-being-effected (CBE) regulation, 21 C.F.R. 314.70(c)(6), however, establishes a limited exception permitting

"the holder of an approved application [to] commence distribution of the [changed] drug product involved upon receipt by the agency of a supplement for the change" if, *inter alia*, the change "add[s] or strengthen[s]" a warning or a statement about administration of the drug to promote safety. 21 C.F.R. 314.70(c)(6)(iii)(A) and (C); see *Wyeth*, 555 U.S. at 571.

Although the CBE regulation applies to both brand-name and generic drugs, see 21 C.F.R. 314.97, under FDA's current interpretation of its regulations, a generic drug's "labeling" must, with exceptions not relevant here, be "consistent with that for the listed [brand-name] drug." 21 C.F.R. 314.150(b)(10). The Court in *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011), "defer[red] to the FDA's interpretation of its CBE and generic labeling regulations" to conclude that a generic drug manufacturer has "an ongoing federal duty of 'sameness'" for its generic-drug labeling that prohibits it from using the CBE process unilaterally to change its labeling before the corresponding brand-name drug's labeling has been changed. *Id.* at 2575 (citation omitted).

When the brand-name drug's labeling has been updated, however, a generic drug manufacturer's duty of sameness requires that it update its labeling accordingly. FDA has stated in non-binding guidance that a generic drug manufacturer "should routinely monitor" for changes in a RLD's labeling, is "responsible for ensuring" that it makes corresponding changes to its generic-drug labeling, and should implement such changes "at the very earliest time possible." FDA, *Guidance for Industry: Revising ANDA Labeling Following Revision of the RLD Labeling* 5 (May 2000) (*Labeling Guidance*), http://www.fda.gov/downloads/

drugs/guidancecomplianceregulatoryinformation/guidances/ucm072891.pdf.[1]

c. Manufacturers may communicate updated warnings directly to doctors through "Dear Health Care Provider" (DHCP) letters, colloquially referred to as "Dear Doctor" letters. See 21 C.F.R. 200.5. Such letters can be appropriate to convey "important safety concern[s]," such as "clinically important new information about a known adverse reaction." FDA, *Guidance for Industry: Dear Health Care Provider Letters* 3-4 (Jan. 2014), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm233769.pdf (non-binding guidance).

DHCP letters are a form of labeling, 21 C.F.R. 202.1(*l*)(2), and must therefore be consistent with and not contrary to the relevant "approved or permitted" labeling, 21 C.F.R. 201.100(d)(1). In *Mensing*, this Court "defer[red] to [FDA's]" construction of its regulations to conclude that, where the labeling of a brand-name RLD has not been updated to include a substantial new warning, a generic drug manufacturer cannot issue a DHCP letter with that warning because the

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[1] Since 2007, FDA has possessed authority in certain circumstances to require a drug manufacturer to make labeling changes to address new safety information. 21 U.S.C. 355(*o*)(4). FDA has explained in non-binding guidance that if FDA notifies a generic drug manufacturer that it has required and approved a change to a RLD's labeling under that provision, the generic drug manufacturer should submit a CBE supplement to its ANDA "within 30 days" of the notification. FDA, *Guidance for Industry: Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD&C Act* 11 (July 2013), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm250783.pdf.

letter would not be consistent with the "approved" labeling. 131 S. Ct. at 2576.

2. Merck & Company holds an approved NDA for alendronate sodium, a bisphosphonate prescribed for the treatment of osteoporosis, which Merck markets under the brand name Fosamax. Petitioners are generic drug manufacturers that hold ANDAs for generic versions of that drug. Pet. App. 3a-4a.

In March 2010 and January 2011, FDA approved updates to Fosamax's labeling to address the risk of femoral fracture. Pet. App. 57a-58a. Olga Pikerie, the real party in interest in the mandamus proceedings below (hereinafter respondent), took Fosamax or generic alendronate sodium from 2006 until she suffered a femoral fracture in April 2011. *Id.* at 4a, 79a-80a.

3. a. Respondent brought this tort action in California state court against petitioners and others. Pet. App. 34a-99a (complaint). As relevant here, respondent alleges that petitioners breached their "duty to warn" of their generic drugs' risks. *Id.* at 65a, 67a. Respondent contends, *inter alia*, that petitioners could have but did not provide such a warning by (a) timely updating their labeling to warn of the risk of femoral fractures after FDA approved the 2010 and 2011 changes to Fosamax's labeling, and (b) otherwise communicating an appropriate warning in DHCP letters to physicians. *Id.* at 73a-75a, 77a, 79a. Respondent alleges that her injuries would have been avoided if petitioners had "properly disclosed [their drugs'] risks." *Id.* at 80a; see *id.* at 66a-67a.

Petitioners filed a demurrer asserting preemption defenses, which the trial court rejected. Pet. App. 29a-30a. The court concluded that respondent's com-

plaint stated causes of action that are "not preempted," *id.* at 30a, and certified its decision for interlocutory review, *id.* at 31a-32a.

b. The California Fourth District Court of Appeal denied petitioners' interlocutory petition for review. Pet. App. 1a-28a. The court concluded that respondent's complaint properly stated causes of action that "are not preempted by federal law," including claims based on petitioners' alleged "fail[ure] to adequately warn [respondent] of the safety issues regarding the[ir] products." *Id.* at 2a-3a. The court reasoned that the "only issue" litigated under petitioners' demurrer was whether respondent's claims were impliedly preempted on the ground that federal law made it "impossib[le]" for petitioners to comply with their state-law tort duties. *Id.* at 9a. The court concluded that petitioners could have taken at least two actions that would not have been preempted under that test. *Id.* at 11a-27a.

First, the court of appeal concluded that the complaint sufficiently alleged that petitioners could have complied with both their "state tort law duty to prevent harm" and their "federal duty" to update their labeling to "match the Fosamax label" by updating their generic-drug labeling to warn of the risk of femoral fractures after Fosamax's labeling had been updated. Pet. App. 13a, 15a; see *id.* at 11a-22a. The court accordingly rejected petitioners' contention that such action would run afoul of "impossibility preemption." *Id.* at 15a.

The court of appeal rejected petitioners' reliance on 21 U.S.C. 337(a) and *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), in arguing respondent could not base her state-law tort claims on

petitioners' federal duty to update their labeling. Pet. App. 19a-22a. The court explained that *Buckman* limited its analysis to fraud-on-the-FDA claims existing solely by virtue of the FDCA, and that *Buckman* itself recognized that "'certain state-law causes of action[] that parallel federal safety requirements' were permitted." *Id.* at 20a-21a (quoting *Buckman*, 531 U.S. at 353). Respondent's warning-based claims, the court concluded, rest on "state law tort principles of a drug manufacturer's duty to the consumers of its product" that parallel federal-law duties and therefore are not preempted. *Ibid.*

Second, the court of appeal concluded that respondent sufficiently alleged that petitioners could have complied with their state-law duty to adequately communicate safety information by sending DHCP letters. Pet. App. 22a-27a. The court determined that "[i]t would not have been impossible for [petitioners] to send [DHCP] letters advising health care professionals of the risks identified in the 2010 and 2011 Fosamax label changes." *Id.* at 22a-23a.

Finally, the court of appeal observed that the trial court rejected petitioners' pleading-stage demurrer on two other grounds. Pet. App. 28a. But because it had determined that respondent's complaint survived dismissal on the grounds discussed above, the court concluded that it "need not reach" in its interlocutory decision the trial court's other bases for rejecting petitioners' demurrer. *Ibid.*

c. Petitioners petitioned the California Supreme Court for discretionary review, see Cal. Ct. R. 8.500(b), but that court denied review. Pet. App. 33a.

DISCUSSION

Petitioners seek review of an interlocutory decision by an intermediate state appellate court that has only partially resolved petitioners' contentions that the state-law duty-to-warn claims in respondent's complaint are preempted by federal law. In our view, this Court lacks jurisdiction to review that state-court decision. 28 U.S.C. 1257. In any event, the court of appeal correctly concluded that respondent's state-law duty-to-warn claims are not preempted. To the extent that lower courts have disagreed about the status of such state-law tort claims under the FDCA, it would be premature for this Court to address that issue at this time: The preemption issues raised in petitioners' interlocutory petition have not been passed upon by the California Supreme Court; those issues have not been fully ventilated in the lower courts; the record would benefit from further development before plenary review; and FDA is considering regulatory changes that, if adopted, would have a significant impact on federal requirements for generic-drug labeling. This Court's review is therefore unwarranted.

I. THIS COURT LACKS JURISDICTION TO REVIEW THE STATE COURT OF APPEAL'S INTERLOCUTORY DECISION

Section 1257 grants this Court jurisdiction over certain "[f]inal judgments or decrees" of a state court that rest on federal law when the "final" decision is rendered directly by "the highest court of a State," 28 U.S.C. 1257(a), or by "a lower state court if the 'state court of last resort' has denied discretionary review," *Gonzalez* v. *Thaler*, 132 S. Ct. 641, 656 (2012) (quoting Sup. Ct. R. 13.1). Section 1257 thereby "establishes a firm final judgment rule," *Jefferson* v. *City of Tar-*

rant, 522 U.S. 75, 81 (1997), limiting this Court's "power to intervene in State litigation," and thereby safeguarding the "smooth working of our federal system," *Radio Station WOW, Inc.* v. *Johnson*, 326 U.S. 120, 124 (1945).

Cox Broadcasting Corp. v. *Cohn*, 420 U.S. 469 (1975), identifies four "exceptional categories" of state-court decisions that can be deemed "'final' on the federal issue despite the ordering of further proceedings in the lower state courts." *Johnson* v. *California*, 541 U.S. 428, 429-430 (2004) (per curiam). The fourth category, on which petitioners rely (Reply Br. 2-5), involves cases in which (1) "the federal issue has been finally decided in the state courts"; (2) "reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action"; (3) the party seeking this Court's review might prevail on non-federal grounds in forthcoming state proceedings, making this Court's review of the federal issue "unnecessary"; and (4) "a refusal immediately to review the state-court decision might seriously erode federal policy." *Cox*, 420 U.S. at 482-483. We do not believe this case satisfies that test.

1. It does not appear that reversal by this Court "would be preclusive of any further litigation on the relevant cause of action." *Cox*, 420 U.S. at 482. Even if respondent's multiple legal bases for her warning-based claim (Pet. App. 84a-85a, 86a-88a, 95a) were regarded as multiple causes of action under state law, they are supported by the same underlying factual allegations (*id.* at 48a-69a, 72a-81a) against which petitioners have asserted their preemption defenses. And because the court of appeal addressed only two of the bases for rejecting petitioners' demurrer, *id.* at

28a, reversal by this Court would necessitate a remand for further litigation to review the trial court's two other grounds for advancing this case beyond the pleading stage.

2. Petitioners argue (Reply Br. 3) that "a federal preemption defense necessarily implicates important federal policies" as required by the fourth *Cox* category. Petitioners thus seemingly contend that all claims ultimately resting on the Supremacy Clause necessarily satisfy this prong of that exception to finality. But this Court has repeatedly explained that *Cox*'s fourth exception "does not apply" where the party invoking the Court's jurisdiction fails to make a "convincing claim of erosion of federal policy that is not common to all decisions" rejecting a claim of the same sort. *Johnson*, 541 U.S. at 430. If it were otherwise, "'the fourth exception [would] swallow the rule.'" *Ibid.* (quoting *Flynt* v. *Ohio*, 451 U.S. 619, 622 (1981) (per curiam)); accord *Florida* v. *Thomas*, 532 U.S. 774, 780 (2001).

This Court accordingly has analyzed its jurisdiction to review interlocutory state-court decisions involving preemption claims by determining whether deferring review in the context of the particular case could "seriously erode federal policy," *Cox*, 420 U.S. at 483, rather than base jurisdiction on the bare fact that a preemption defense is asserted. See, *e.g.*, *Goodyear Atomic Corp.* v. *Miller*, 486 U.S. 174, 179-180 (1988) (deferring review of state supreme court decision denying preemption could "seriously erode federal policy" because it would allow "direct state regulation of nonradiological hazards at * * * the only nuclear facility producing nuclear fuel for the Navy's nuclear fleet" and had "important implications for the regu-

lation of federally owned nuclear production facilities"); *Belknap, Inc.* v. *Hale*, 463 U.S. 491, 497 n.5 (1983) (permitting "proceedings to go forward in the state court" would involve "serious risk of eroding" federal policy of requiring that labor disputes be heard by the National Labor Relations Board, not state courts; following *Construction & General Laborers' Union* v. *Curry*, 371 U.S. 542 (1963)).

Here, petitioners' assertion (Reply Br. 3) that this case "undermines the exclusive enforcement discretion Congress granted FDA" does not in itself demonstrate that declining "*immediately* to review the state-court decision might seriously erode federal policy," *Cox*, 420 U.S. at 483 (emphasis added). As this Court has explained, "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," *Wyeth* v. *Levine*, 555 U.S. 555, 575 (2009), especially not in the sweeping and categorical manner petitioners suggest. In particular, petitioners err in contending that *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), broadly bars tort actions under state law that parallel duties under the FDCA and implementing regulations. *Wyeth* concluded, for example, that Congress "deci[ded] not to pre-empt common-law tort suits," that FDA has "traditionally regarded state law as a complementary form of drug regulation," and that "[s]tate tort suits * * * provide incentives for drug manufacturers to disclose safety risks promptly." 555 U.S. at 578-579.

At bottom, this case raises a narrower question: whether the particular types of claims here are preempted under the FDCA and current regulations applicable to generic drugs when FDA has approved

changes to the labeling of the RLD. In these circumstances, and because this is an action seeking only money damages, any outcome-determinative error in adjudicating petitioners' asserted "federal preemption defense" (Reply Br. 3) can, without substantially eroding federal policy, be addressed later if a final judgment awarding damages is ultimately entered.

II. THE INTERMEDIATE APPELLATE COURT'S INTERLOCUTORY PREEMPTION RULING DOES NOT WARRANT CERTIORARI AT THIS TIME

In any event, the interlocutory decision of the state court of appeal does not warrant review. The court of appeal correctly rejected petitioners' preemption defenses, and this Court's review would be premature.

A. Petitioners' *Buckman*-Based Contentions Are Incorrect And Do Not Warrant Review

Petitioners invoke 21 U.S.C. 337(a) and *Buckman* to argue (Pet. 23-31) that respondent's state-law duty-to-warn claims are impliedly preempted to the extent that respondent relies on petitioners' federal duty to update their labeling to match Fosamax's updated labeling. That contention is without merit.

1. In *Buckman*, the plaintiffs alleged injuries from medical devices that had been cleared for sale by FDA through the efforts of the defendant, a consultant that assisted the device manufacturer in navigating the federal regulatory process. 531 U.S. at 343, 346. The defendant's efforts, the plaintiffs claimed, involved a fraud on FDA, and "[h]ad [those fraudulent] representations not been made, the FDA would not have [cleared] the devices, and plaintiffs would not have been injured." *Id.* at 344.

This Court held those claims preempted, relying on several considerations. First, the putative state-law claims sought to police fraud on a federal agency by entities it regulates, a matter of exclusively federal character over which FDA possessed ample direct authority. *Buckman*, 531 U.S. at 347-350. Such state-law claims of fraud, the Court reasoned, "would exert an extraneous pull" (*id.* at 353) on the relationship between FDA and those it regulates. *Id.* at 350-351. Additionally, the claims in *Buckman* did not "rely[] on traditional state tort law" (*id.* at 353) because the defendant was not the manufacturer of the devices and therefore did not have a manufacturer's duty to warn purchasers of its products' safety risks. Rather, the plaintiffs relied on a theory based on an alleged fraud of FDA that "exist[ed] solely by virtue of the FDCA." *Ibid.* The Court indicated that such enforcement of the FDCA is by statute vested exclusively in the United States. *Id.* at 349 n.4, 352 (citing 21 U.S.C. 337(a)).

Respondent's claims differ from those in *Buckman* in that petitioners allegedly had a state-law duty to warn that would exist even absent the FDCA. See, *e.g.*, *John Norton Farms, Inc.* v. *Todagco*, 177 Cal. Rptr. 215, 228 (Cal. Ct. App. 1981) ("If the seller of a product knows that the product sold by him is dangerous * * * he is negligent if he fails to warn of the latent defect."). The state court of appeal understood respondent's complaint to assert duty-to-warn claims that rest on "state law tort principles of a drug manufacturer's duty to the consumers of its product," even though respondent alleged that petitioners could provide such warnings by updating their labels as required by federal law. Pet. App. 20a-21a. Thus, as the

case comes to the Court, respondent seeks to invoke traditional state tort law, not to enforce the FDCA itself.

The FDCA and FDA's implementing regulations can, of course, limit the actions a drug manufacturer can take, and state-law duties that conflict with such federal limitations would be preempted. A generic drug manufacturer, for instance, cannot currently change its labeling to identify a new risk if such a change would depart from the labeling of the relevant brand-name counterpart. *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2577-2578 (2011). But such limits do not suggest that a state-law duty to warn is preempted merely because a drug manufacturer could satisfy that duty only by taking actions that *comport* with federal law. *Buckman* thus recognized that "state-law causes of actions that parallel federal safety requirements" may be permitted, and it limited its preemption analysis to "claims [that] exist solely by virtue of the FDCA." 531 U.S. at 353.[2]

Indeed, respondent's claims closely resemble the state-law duty-to-warn claim that *Wyeth* held *not* preempted. The plaintiff in *Wyeth* alleged that Phenergan's labeling had insufficiently warned of the drug's risks. 555 U.S. at 560, 562, 565. The FDCA and its implementing regulations, the Court recog-

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[2] Petitioners' assertion (Pet. 29-30) that the government argued that private tort claims against drug manufacturers undermine "FDA's broad enforcement discretion" is based on misleading partial quotations from the government's *Buckman* brief. Omitted portions of the relevant text make clear that the government argued that "fraud-on-the-FDA claims" conflict with FDA's strong interest "to decide for itself whether it has been defrauded" and the appropriate remedy to seek for such fraud. U.S. Amicus Br. at 23-24, *Buckman*, *supra* (No. 98-1768).

nized, embody the "central premise" that "the [drug] manufacturer bears responsibility for the content of its label at all times" and that the manufacturer is thus "charged * * * with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 570-571. *Wyeth* explained, for instance, that when Congress enacted 21 U.S.C. 355(*o*) in 2007 to grant FDA authority to require manufacturers to revise their labeling in light of new post-approval safety-related information, Congress "referred specifically to the CBE regulation" in 21 C.F.R. 314.70(c)(6)(iii), which permits drug manufacturers to make certain safety-related changes to their labeling and "reflects the manufacturer's ultimate responsibility for its label." 555 U.S. at 571 (discussing 21 U.S.C. 355(*o*)(4)(I)). *Wyeth* further determined that "[s]tate tort suits"—and "[f]ailure-to-warn actions, in particular"—"provide incentives for drug manufacturers to disclose safety risks promptly" and "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id.* at 579.

In light of "Congress' decision not to pre-empt [such] common-law tort suits" and the "longstanding coexistence of state and federal law" in this area, *Wyeth* concluded that state-law duty-to-warn claims are not preempted, 555 U.S. at 578, 581, if the drug manufacturer can "comply with both federal and state requirements" by providing such warnings consistent with federal law. See *id.* at 573. And because "[t]he CBE regulation permitted Wyeth to unilaterally strengthen its warning," the state-law duty-to-warn claim in *Wyeth* was not preempted. *Ibid.* This case is no different. Petitioners no longer dispute that it is

not impossible to comply with the relevant federal and state duties. Pet. 24.[3] And if petitioners' expansive reading of *Buckman* were correct, *Buckman* presumably would have barred the duty-to-warn claims in *Wyeth*.

Petitioners argue (Pet. 10, 25) that *Buckman* should bar respondent's action because her complaint refers to the generic manufacturers' failure to update their labeling in accordance with federal law and asserts a claim of negligence *per se* based on that failure. Pet. 25. But "a complaint alleging a violation of a federal statute as an element of a state cause of action" is still a state-law, rather than a federal-law, claim, *Merrell Dow Pharm. Inc.* v. *Thompson*, 478 U.S. 804, 817 (1986), and, as discussed, the state-law duty to warn here exists independently of federal law. California's *per se* negligence doctrine, in turn, merely establishes a rebuttable presumption of negligence. See, *e.g.*, *Ramirez* v. *Nelson*, 188 P.3d 659, 665-666 (Cal. 2008); Cal. Evid. Code § 669(a) and (b)(1). Proof of a violation of federal law thus is neither necessary nor sufficient to establish liability under state law.

Petitioners suggest (Pet. 30-31) that allowing private plaintiffs to bring actions against generic manufacturers for failing to promptly update their labeling

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[3] The state court addressed only petitioners' *Buckman* and impossibility-preemption defenses. This case therefore currently presents no occasion to consider whether a state-law duty to warn would be impliedly preempted as frustrating the objects or purposes of FDA regulations if it were to require a warning on a timeframe that did not allow a reasonable period for the generic manufacturer to prepare and submit a CBE supplement to its ANDA to update its labeling. Cf. Pet. 30-31 (discussing manufacturer's potential liability for not changing labeling the day after the RLD's labeling change is approved).

would impinge on FDA's enforcement discretion. To the contrary, such actions against generic manufacturers who do not promptly update their labeling align with FDA's priorities. FDA advises generic drug manufacturers to "routinely monitor * * * for information on changes in labeling" and to make appropriate revisions "at the very earliest time possible." *Labeling Guidance* 5. As this Court has explained, FDA "has limited resources to monitor the 11,000 drugs on the market" and, as in *Wyeth*, "[f]ailure-to-warn actions" like that here "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Wyeth*, 555 U.S. at 578-579.

2. Certiorari is unnecessary to resolve a division of authority on the first question presented. A decision of an intermediate state appellate court does not create a conflict of the sort warranting review by this Court, see Sup. Ct. R. 10(b), and the California Supreme Court has not rendered a decision in this case.[4] Petitioners instead contend (Pet. 4, 19-20) that *Fulgenzi* v. *PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013), which the state court of appeal followed, Pet. App. 13a-15a, conflicts with *Morris* v. *PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013) (per curiam). Those decisions do not present a clear conflict warranting review.

The *Morris* court stated (without elaboration) that "a claim that [a generic drug manufacturer] breached a federal labeling obligation [by failing to incorporate an FDA-approved warning in its labeling] sounds

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[4] The intermediate Iowa court decision on which petitioners rely (Pet. 4, 19-20) has been overturned. See *Huck* v. *Trimark Physicians Grp.*, 834 N.W.2d 82 (Iowa Ct. App. 2013), vacated *sub nom. Huck* v. *Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014).

exclusively in federal (not state) law, and is preempted." 713 F.3d at 777 (citing 21 U.S.C. 337(a) and *Buckman*, 531 U.S. at 349 n.4). The Fifth Circuit has twice repeated that statement without further analysis. See *Johnson* v. *Teva Pharm. USA, Inc.*, 758 F.3d 605, 612 (2014); *Lashley* v. *Pfizer, Inc.*, 750 F.3d 470, 475 (2014) (per curiam). In each of those cases, the plaintiff failed (or arguably failed) even to plead a claim based on the failure to update a generic-drug label and the Fifth Circuit identified antecedent deficiencies with the plaintiffs' labeling contentions. But even if *Morris*'s statement were deemed binding on future Fifth Circuit panels, cf. *In re Hearn*, 376 F.3d 447, 453 n.5 (5th Cir. 2004) (Fifth Circuit decisions should not be read as adopting "alternative rationales or holdings" unless they are "clearly expressed"), it would not establish a conflict warranting review. A "*claim that* [a generic drug manufacturer] *breached a federal* labeling obligation," *Morris*, 713 F.3d at 777 (emphasis added), standing alone, could be understood as solely a federal claim that Section 337(a) might prohibit. But as *Fulgenzi* recognized, an independent claim "based on traditional state-tort-law principles" that "parallel[s] federal safety requirements" but does not "'exist solely by virtue of'" the FDCA is not preempted. 711 F.3d at 586 (quoting *Buckman*, 531 U.S. at 353). Both conclusions appear consistent and thus present no issue warranting review. In all events, the Fifth Circuit's conclusory and unexplained statement would be an insufficient basis for certiorari.

B. Petitioners May Use Dear Health Care Provider Letters To Communicate Warnings Consistent With Federal Law

Petitioners separately contend (Pet. 32-33) that the state court of appeal erred in rejecting their impossibility-preemption defense based on its conclusion that petitioners could, consistent with Federal law, "send Dear Doctor letters advising health care professionals of the risks identified in the 2010 and 2011 Fosamax label changes," see Pet. App. 23a. In petitioners' view (Pet. 32), *Mensing* teaches that a generic drug manufacturer cannot send such letters before the relevant brand-name manufacturer does. Petitioners are incorrect, and their contentions merit no further review at this time.

1. In *Mensing*, the plaintiffs argued that a state-law duty to warn required manufacturers of generic versions of Reglan to revise their labeling to provide a stronger warning of their products' risks. 131 S. Ct. at 2574, 2577-2578. This Court held that duty preempted because, under FDA's interpretation of its regulations, the generic manufacturers could not use the CBE process to change the proposed labeling in their ANDAs before the brand-name labeling had been changed to include the warning. *Id.* at 2575, 2578. The plaintiffs also argued that the generic manufacturers could have sent DHCP letters to provide additional warnings. *Id.* at 2576. The government, in its brief, explained that "a DHCP letter can be an appropriate way to bring new information to the attention of medical professionals" and that "nothing in the FDCA or FDA's regulations categorically forbids an ANDA holder from unilaterally sending [such] a DHCP letter." U.S. Amicus Br. at 18-19, *Mensing*,

supra (Nos. 09-993, 09-1039, 09-1501) (U.S. *Mensing* Br.). But because the very purpose of the proposed letter would have been to "depart from * * * the approved labeling" about relevant risks, it would have violated 21 C.F.R. 201.100(d)(1)'s requirement that the letter be "consistent with and not contrary to" such labeling. U.S. *Mensing* Br. 19. "Depending on its content," the government explained (*ibid.*), a DHCP letter could also be misleading in violation of 21 C.F.R 314.150(b)(3) if it implied non-existent therapeutic differences between the generic and brand-name drugs. This Court "defer[red] to the FDA['s]" interpretation of its regulations and thus concluded that the *Mensing* defendants could not use DHCP letters "to issue additional warnings." 131 S. Ct. at 2576.

Mensing did not address the issue here: whether a DHCP letter could be used by a generic manufacturer to communicate warnings *already present* in the relevant brand-name labeling. Petitioners, for instance, assert (Pet. 31) that one petitioner submitted a CBE supplement to FDA to update its generic-drug labeling within six weeks of the March 2010 and January 2011 FDA approvals of Fosamax's labeling changes. If a generic manufacturer has submitted such a CBE supplement, and FDA has approved it, the generic manufacturer may "unilaterally" disseminate a DHCP letter to communicate the new labeling warnings even if the brand-name manufacturer has not done so, see U.S. *Mensing* Br. 18, absent circumstances not present here, cf. 21 U.S.C. 355-1(e)(3) and (i)(2)(A). Such letters would not imply any difference between the

generic and brand-name drugs or otherwise run afoul of FDA's regulatory requirements.[5]

2. Petitioners cite (Pet. 33) decisions that support petitioners' view that *Mensing* precludes any generic manufacturer from sending a DHCP letter unless the relevant brand-name manufacturer has done so first. *Germain* v. *Teva Pharm., USA, Inc.*, 756 F.3d 917, 932-933 (6th Cir. 2014); *Guarino* v. *Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013); *Morris*, 713 F.3d at 777 (5th Cir.). Without examining the relevant regulations or considering FDA's views, *Morris* simply concluded that *Mensing* shows that "the inquiry is whether the brand-name manufacturers sent out a warning, not whether the proposed warning to be disseminated contains substantially similar information as the label." 713 F.3d at 777. *Guarino* and *Germain* restate *Morris*'s conclusions without further analysis. Although those courts erred in their reading of *Mensing*, this Court's review would be premature.

The California Supreme Court has not addressed the relevant issues and an intermediate state court decision, like the decision at issue here, does not create a conflict warranting this Court's review. See Sup. Ct. R. 10(b). That principle is particularly significant

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[5] Whether a generic manufacturer may send such a DHCP letter *before* a CBE supplement is submitted to or approved by FDA to conform the generic drug's labeling to that approved for the RLD are different questions that turn on whether the letter would be consistent with the drug's "permitted" labeling under 21 C.F.R. 201.100(d)(1), even if its "approved" labeling does not yet contain the new FDA-approved labeling for the RLD. Because of the facts presented in *Mensing*, the government's *Mensing* brief (at 18-19) discussed whether the proposed DHCP letter there would be consistent with "approved" labeling under Section 201.100(d)(1) without addressing the question of "permitted" labeling.

in the context of interlocutory rulings, because the decision of the state intermediate court may not survive future state supreme court review. Moreover, further percolation in the lower courts would permit a more careful consideration of *Mensing* and the government's position.

C. Other Prudential Considerations Counsel Against Review

1. This case's interlocutory posture limits the record that would be before the Court if certiorari were granted. The pleading-stage record, for instance, does not contain information documenting the substance or timing of the various petitioners' responses to the March 2010 and January 2011 Fosamax labeling changes. It would be advisable to allow the case to proceed further to develop the factual record appropriate for plenary review.

2. Review of the preemption issues in this case would also be premature in light of pending FDA regulatory changes. FDA has proposed a regulation that would "enable ANDA holders to update product labeling promptly to reflect certain types of newly acquired information related to drug safety, irrespective of whether the revised labeling differs from that of the RLD." 78 Fed. Reg. 67,985, 67,986 (Nov. 13, 2013). That regulation, if accepted in final form, "would create parity among [application] holders," eliminating many of the different labeling duties for generic and brand-name manufacturers identified in *Mensing*. See *id.* at 67,989. That regulation would also create new mechanisms for notifying manufacturers of approved CBEs and "establish a 30-day timeframe in which all ANDA holders would be required to submit a CBE[] supplement with conforming labeling

changes after FDA approval of a revision to the labeling for the [corresponding brand-name drug]." *Id.* at 67,986. FDA's regulatory agenda indicates that FDA may issue a final rule by September 2015. See http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201410&RIN=0910-AG94.

As FDA has explained, these changes, if adopted, "may eliminate the preemption of certain failure-to-warn claims with respect to generic drugs." 78 Fed. Reg. at 67,989. Although FDA's proposal is not retroactive and would not apply to pending failure-to-warn claims, it would circumscribe the number of cases affected by the outcome of this litigation and limit the significance of a ruling by this Court in this case.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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