No. 18-803

IN THE
Supreme Court of the United States

WENDY B. DOLIN,

Petitioner,

v.

GLAXOSMITHKLINE LLC,

Respondent.

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Under *Wyeth v. Levine*, 555 U.S. 555 (2009), federal law preempts a state failure-to-warn claim where there is clear evidence that the Food & Drug Administration (FDA) would have rejected the warning that the plaintiff claims state law requires. Under *Wyeth* and *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), a state failure-to-warn claim is also preempted if a defendant could not "unilaterally" add the warning that plaintiff claims state law requires.

The question presented is:

Whether the Seventh Circuit correctly applied these precedents to the facts of this case, when it held that no reasonable jury could find that federal law permitted petitioner's proposed warning because (1) FDA repeatedly rejected petitioner's proposed warning, and (2) the drug's manufacturer lacked newly acquired information that would have permitted it to change the label unilaterally without prior FDA permission.

RULE 29.6 STATEMENT

GlaxoSmithKline LLC is an indirect wholly-owned subsidiary of GlaxoSmithKline plc, a publicly traded company organized under the laws of England.

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JURISDICTION

The judgment of the court of appeals was entered on August 22, 2018. A petition for rehearing was denied on September 20, 2018 (Pet. App. 67-68). The petition for a writ of certiorari was filed on December 19, 2018. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATEMENT

A. Regulatory Background

1. Under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399, brand manufacturers may not change their drugs' labeling without FDA's prior approval except in very limited circumstances. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612-17 (2011). Under FDA's "Changes Being Effected" (CBE) regulation, brand manufacturers may change their labeling unilaterally "[t]o add or strengthen a … warning," but only to reflect "newly acquired information" that was "not previously submitted to [FDA]." 21 C.F.R. §§ 314.3, 314.70(c)(6)(iii)(A); *see also Wyeth*, 555 U.S. at 568-69. FDA retains authority to later reject such a change. 21 C.F.R. § 314.70(c)(7). Generic manufacturers, for their part, must match their labeling to the corre-

sponding brand-name labels. *Mensing*, 564 U.S. at 612-13.

2. Paxil is a brand-name prescription medication approved by FDA to treat major depressive disorder and other psychiatric disorders. Pet. App. 3, 37. Paxil's active ingredient is paroxetine hydrochloride (paroxetine), a selective serotonin reuptake inhibitor (SSRI). *Id.* at 8. Paroxetine and other SSRIs have improved the lives of hundreds of millions of people suffering from anxiety and depression. GSK C.A. Br. 2 (Dkt. 24).

GlaxoSmithKline LLC (GSK) manufactured and marketed Paxil in the United States from 1992 to 2014, when GSK sold Paxil's New Drug Application to another company. Pet. App. 7, 9, 15. GSK no longer manufactures, markets, or profits from any sale of Paxil in the United States. Generic paroxetine entered the U.S. market in 2003, and by 2010, Paxil retained only 1% of the market. GSK C.A. Br. 6.

For nearly three decades, FDA has rejected any association between any SSRIs, including Paxil, and suicidality past age 24. In 1991, an independent FDA advisory committee found "no credible evidence" that the only SSRI then available increased suicidality for any age group. Pet. App. 9. One year later, FDA approved Paxil's original label without any paroxetine-specific suicide warning, instead requiring that the label warn that the possibility of suicide attempts are inherent in depression. *Id.*

Throughout the 1990s and early 2000s, GSK submitted safety data on Paxil to FDA. Pet. App. 9. In 2004, FDA concluded that SSRIs pose an increased suicidality risk for *pediatric* patients and mandated that SSRI manufacturers, including GSK,

add a warning to that effect on the drug labeling. *Id.* at 10. GSK included the mandatory warning and continued to study the effects of paroxetine on patients of all ages while FDA conducted its own studies on all SSRIs, including Paxil. *Id.* at 9-11. In 2006, based on GSK's re-analysis of Paxil adult-suicidality data using a new FDA classification methodology, GSK unilaterally changed Paxil's labeling under FDA's CBE regulation to add a warning about adult suicidality. *Id.* at 11-12. Although GSK did not believe this re-analysis established a "causal relationship" between paroxetine and suicidality in adults, D. Ct. Dkt. 589-21, at 4 (Sept. 25, 2017), GSK added the adult-suicidality warning out of an abundance of caution.

In November 2006, FDA completed an extensive meta-analysis of 372 placebo-controlled SSRI clinical trials involving nearly 100,000 adult patients. Pet. App. 12-13. FDA found "an elevated risk for suicidality and suicidal behavior among adults younger than 25," but concluded that the "net effect appears to be neutral on suicidal behavior but possibly protective for suicidality for adults between the ages of 25 and 64 and to reduce the risk of both suicidality and suicidal behavior in subjects aged 65 years and older." *Id.* at 13.

Based on its meta-analysis, FDA on May 1, 2007, directed GSK and other SSRI manufacturers to revise their labeling. FDA directed GSK to revise Paxil's labeling "to ensure standardized labeling pertaining to adult suicidality with all of the drugs to treat major depressive disorder." Pet. App. 13. FDA ordered all SSRI labeling to warn of a suicidality risk in persons *24 or under* (as GSK had done since 2006). *Id*. FDA also ordered all SSRI labeling, including Paxil's, to state the following:

> Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older.

D. Ct. Dkt. 589-23, at 2-3 (Sept. 25, 2017); *see* Pet. App. 13-14. FDA required all SSRI labeling to include this language "verbatim." *Id.* at 14. Paxil's warning today contains this identical language. *Id.* at 15-16. In other words, since May 1, 2007, FDA has required manufacturers to disclaim any adult-suicidality risk past age 24 from SSRIs and, *a fortiori*, has barred manufacturers from unilaterally changing their labeling to warn of such risk unless manufacturers comply with the agency's CBE regulation.

3. Following FDA's decision to require standardized labeling for all SSRIs, GSK asked FDA four times for approval to retain a Paxil-specific adult-suicidality warning in addition to the standardized warning for all SSRIs. Pet. App. 14-15. FDA rejected each and every request. *Id.*

B. Procedural Background

1. In 2010, petitioner's husband, Stewart Dolin, committed suicide at age 57. At the time, Mr. Dolin was being treated with generic paroxetine made by a generic drug manufacturer, Mylan, Inc. Petitioner filed the instant suit against Mylan and GSK, alleging that paroxetine increases the risk of suicide in adults, that it caused Mr. Dolin's suicide, and that both companies negligently failed to warn of that risk. Pet. App. 16 & n.1. The district court granted Mylan's motion to dismiss under *Mensing* and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013).

Pet. App. 16 & n.1. And although GSK did not make the drug Mr. Dolin ingested, petitioner claimed that, because GSK developed Paxil's labeling and federal law requires generic paroxetine's labeling to match Paxil's, GSK was responsible for all injuries caused by a failure to warn regardless of the drug manufacturer. *Id.* at 16. Following a trial, the jury returned a $3 million verdict for petitioner. *Id.* at 2. The district court denied GSK's motions for judgment as a matter of law. *Id.* at 30-61.

2. The court of appeals unanimously reversed in an opinion authored by Judge Hamilton and joined by Chief Judge Wood and Judge Sykes. Pet. App. 1-29. GSK had raised three grounds for reversal: that brand manufacturers could not be held liable to consumers of generic manufacturers' drugs; that federal law preempted the failure-to-warn claim; and that petitioner presented insufficient evidence to support the jury's conclusion that any failure-to warn caused Mr. Dolin's suicide. *Id.* at 4. Because the court of appeals reversed the jury's verdict on preemption, the court did not address GSK's other contentions. *Id.* at 29.

As to preemption, the court acknowledged that this Court is poised to resolve a disagreement among the circuits about whether preemption under *Wyeth v. Levine* is a factual question for the jury or a legal question for the court. Pet. App. 20-21 (citing *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290; *In re Fosamax Prods. Liab. Litig.*, 852 F.3d 268, 282 (3d Cir. 2017)). But the court of appeals held that it "need not determine in this case whether preemption under *Levine* involves a factual question for the jury" because "no reasonable jury could find that the FDA would have approved an adult-suicidality warning for Paxil under the CBE regulation." *Id.* at 22.

Turning to the merits, the court explained that under *Wyeth* and *Mensing*, "Dolin's state-law claim against GSK is preempted if GSK could not have added [petitioner's proposed] warning" and that "[t]o add a warning through the CBE regulation, GSK needed newly acquired information about paroxetine that would allow it to add a warning about suicide risk in adults." Pet. App. 19. The court further recognized that "even if GSK had newly acquired information along these lines, GSK can still succeed on its preemption defense if there is clear evidence that the FDA would have rejected the adult-suicidality warning that plaintiff argues was tortiously omitted." *Id.* at 19-20. The court then found for GSK on both of these issues. The court held that, "as a matter of law, (1) there is clear evidence that the FDA would have rejected [petitioner's proposed] warning in 2007, and (2) GSK lacked new information after 2007 that would have allowed it to add an adult-suicidality warning under the CBE regulation." *Id.* at 20.

With respect to the first holding, the court explained that "undisputed evidence" demonstrated that FDA rejected petitioner's proposed adult-suicidality warning in 2007. Pet. App. 22. The court emphasized that FDA "ordered GSK to remove a paroxetine-specific warning of increased suicide risk in adults from the paroxetine label," *id.*, and that FDA denied GSK's "four requests [to FDA] to reconsider," *id.* at 24. The court explained that "no reasonable jury could find otherwise." *Id.* at 23.

The court rejected, as "an unreasonable interpretation of the discussions between the FDA and GSK," petitioner's assertion that FDA objected to the *placement* of the suicidality warning within the labeling, but not to its *content*. Pet. App. 24. The court also rejected out of hand petitioner's argument that

GSK should have requested a formal meeting with FDA to "persuade[]" the agency to change its mind "after already asking four times to include that warning and being told no four times." *Id.* at 25-26.

The court of appeals further held that "GSK lacked new information after 2007 that would have allowed it to add an adult-suicidality warning under the CBE regulation." Pet. App. 20. The court explained that petitioner "failed to offer evidence" that, between FDA's rejection of the paroxetine-specific warning in 2007 and Mr. Dolin's suicide in 2010, GSK acquired any new information about Paxil that would have permitted it to unilaterally change the label under FDA regulations. *Id.* at 27.

The court of appeals subsequently denied a petition for rehearing without dissent. Pet. App. 67-68.

REASONS FOR DENYING THE PETITION

The decision below is correct and does not conflict with the decision of any other court of appeals. The court of appeals correctly articulated and applied *Wyeth v. Levine* and *PLIVA v. Mensing* in holding that federal law preempts petitioner's failure-to-warn claim because "(1) there is clear evidence that the FDA would have rejected the warning in 2007, and (2) GSK lacked new information after 2007 that would have allowed it to add an adult-suicidality warning." Pet. App. 20.

Nor does the Court need to hold this case pending its resolution of *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290 (argued Jan. 7, 2019). The resolution of that case will not alter the disposition of this case, both because there are independent bases for preemption and because the basis for FDA's rejec-

tion of petitioner's proposed warning is not subject to reasonable debate.

I. The Seventh Circuit Correctly Applied *Wyeth* and *Mensing* to Undisputed Facts.

Petitioner seeks this Court's review largely based on her view that the court of appeals incorrectly applied settled preemption law to the facts of this case. But this Court does not sit as a court of error correction. *Ross v. Moffitt*, 417 U.S. 600, 616-17 (1974). To the contrary, the Court generally does not grant certiorari where a petition alleges a "misapplication of a properly stated rule of law" to the facts of a particular case. S. Ct. R. 10. In any event, the unanimous decision of the court of appeals was manifestly correct.

1. Federal law preempts a state failure-to-warn claim unless the defendant could "unilaterally strengthen its [FDA-approved] warning" without preapproval from FDA under the agency's Changes Being Effected (CBE) regulations. *Wyeth*, 555 U.S. at 573; *see also Mensing*, 564 U.S. at 620. The critical question is "whether the private party could *independently* do under federal law what state law requires of it." *Mensing*, 564 U.S. at 620 (emphasis added). And even if the defendant could unilaterally strengthen its warning, federal law still preempts state failure-to-warn claims where there is "clear evidence" that FDA "would … have" rejected the warning that the plaintiff claims state law requires. *Wyeth*, 555 U.S. at 571. In either situation, state law is preempted because "it is impossible for a private party to comply with both state and federal requirements." *Mensing*, 564 U.S. at 618 (internal quotation marks omitted). The court of appeals correctly articulated this standard. Pet. App. 17-19.

Here, petitioner's state-law failure-to-warn claim was preempted for two independent reasons. First, "[t]o add a warning through the CBE regulation, GSK needed newly acquired information about paroxetine that would allow it to add a warning about suicide risk in adults" and, second, "even if GSK had newly acquired information along these lines, GSK can still succeed on its preemption defense if there is clear evidence that the FDA would have rejected the adult-suicidality warning that plaintiff argues was tortiously omitted." Pet. App. 19-20.

Applying the governing law to the "undisputed evidence" presented in this case, the court correctly concluded both that "(1) there is clear evidence that the FDA would have rejected the warning in 2007, and (2) GSK lacked new information after 2007 that would have allowed it to add an adult-suicidality warning under the CBE regulation." Pet. App. 20.

With respect to the "clear evidence" holding, the court noted that "[a]ll four of th[e] evidentiary gaps in *Levine* were filled here." Pet. App. 23. GSK's "four requests" to allow an enhanced warning and four rejections from FDA were "clearly documented" and "not subject to reasonable dispute." Pet. App. 24. Moreover, from 2007, when FDA required all SSRI manufacturers, including GSK, to revise their labels to make clear that SSRIs do not present a suicide risk past age 24, through 2010, when Mr. Dolin committed suicide, federal law required Paxil's label to carry the FDA-mandated warning. Pet. App. 13-14, 27. Here, "[petitioner] failed to offer evidence that GSK acquired new information" after 2007 that would have permitted GSK to change Paxil's label under FDA's CBE regulations. Pet. App. 27. Thus, GSK more than amply showed it was impossible to

revise its label to include the warning that petitioner contended state law required.

2. Petitioner's fact-bound assertions to the contrary lack merit.

First, Petitioner asserts that the court of appeals failed to comply with Rule 50 of the Federal Rules of Civil Procedure by "view[ing] the evidence and draw[ing] all inferences in a manner most favorable to GSK." Pet. 28-30; *see also* Pet. 26, 29-30 (pointing out that the opinion did not expressly discuss the Rule 50 standard). But regardless of whether the panel expressly recited Rule 50's well-established standard, the court unquestionably *applied* the governing legal standard. The court relied on "undisputed" documentary evidence, meaning that no inferences of any sort were drawn because the court had no reason to do so. Pet. App. 22, 27. And its holding—that "no reasonable jury could find that the FDA would have approved an adult-suicidality warning for Paxil"—demonstrates that the court was well aware of and applied Rule 50's "reasonable jury" standard. Pet. App. 22.

Petitioner similarly complains about the court's analysis of the evidence. Specifically, petitioner contends that the court disregarded evidence that FDA had not rejected the petitioner's proposed warning outright but rather rejected GSK's label because GSK proposed warning of adult suicidality in the wrong place on the label. Pet. 30-32, 36-37. That is incorrect. The court of appeals expressly acknowledged petitioner's contention, and found her interpretation of FDA's action "unreasonable." Pet. App. 24. The court recited the undisputed evidence showing that GSK "ask[ed] four times to include [a] warning" and was "told no four times" by FDA. *Id.* at 25-

26. The Seventh Circuit put it bluntly: "Plaintiff asks us to believe that the FDA—after deciding against an adult-suicidality warning based on its own analysis—rejected GSK's warning only because GSK proposed putting it in the wrong place. That is unreasonable." *Id.* at 25.

Petitioner also for the first time in this case argues that allowing GSK to show that it lacked "newly acquired information" to change the Paxil labeling unilaterally constitutes a retroactive application of FDA's 2008 CBE regulations. Pet. 33-34 (citing 21 C.F.R. § 314.70). But the Court does not grant certiorari to address questions that were neither pressed nor passed upon below. *See, e.g.*, *United States v. Williams*, 504 U.S. 36, 41 (1992). This prudent principle is all the more important here, where petitioner has not identified any court of appeals that has even addressed this waived question.

Petitioner's waived retroactivity argument lacks merit in any event. Petitioner concedes that, beginning on September 22, 2008, FDA's regulations required GSK to possess newly acquired information to unilaterally change the Paxil labeling under FDA's CBE regulation. Pet. 33. And petitioner notably does not dispute the Seventh Circuit's determination that GSK lacked any newly acquired information after 2007. Pet. App. 26-28. Petitioner rather appears to theorize that GSK could somehow have altered its labeling sometime after FDA's mandated class-wide warning in 2007 but before the 2008 CBE regulation took effect.

That is wrong for multiple reasons. For one, the 2008 CBE regulation codified existing practice. As the Solicitor General explained to this Court in *Wyeth*, "FDA interpret[ed] [the pre-2008 CBE] regula-

tion to permit changes without prior approval only to address 'newly discovered risks' for which there is sufficient evidence of causal association with the drug."[1] Moreover, the retroactivity issue is wholly academic, as resolution of the question does not alter the outcome of this case. Had GSK attempted unilaterally to employ the CBE process prior to September 22, 2008, FDA would have rejected the proposed warning, and so petitioner's claims would be preempted for that reason alone. FDA had warned GSK in 2007 that "[f]ailure to" implement the class warning "could make your product misbranded." D. Ct. Dkt. 589-49, at 2 (Sept. 25, 2017). FDA would not have suddenly reversed course in 2008 without any new evidence.

Finally, petitioner asserts that GSK's preemption defense should be adjudicated in light of the First Amendment. Pet. 37-38. This one-paragraph argument was neither pressed nor passed upon below. *See, e.g.*, *Williams*, 504 U.S. at 41. And petitioner further fails to develop her theory in the petition. Indeed, it is unclear what petitioner is even arguing. No one is restricting petitioner's speech, and petitioner does not have standing to assert GSK's First

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[1] Brief for the United States as Amicus Curiae Supporting Petitioner at 4, *Wyeth v. Levine*, 555 U.S. 555 (2009) (No. 06-1249); *see also* New Drug and Antibiotic Regulations, 47 Fed. Reg. 46,622, 46,623 (Oct. 19, 1982) ("These supplements would describe changes placed into effect to correct concerns about newly discovered risks from the use of the drug."); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2850 (Jan. 16, 2008) (amending CBE regulation "to make explicit the agency's understanding that a sponsor may utilize the limited CBE provisions only to reflect *newly acquired* safety information").

Amendment rights. *See Allen v. Wright*, 468 U.S. 737, 751 (1984).

In sum, petitioner offers no reason for this Court to revisit the Seventh Circuit's application of settled law to the evidence presented in this case. The fact that petitioner disagrees with the outcome hardly gives rise to an issue that warrants this Court's review.

II. The Decision Below Does Not Implicate a Circuit Split.

Petitioner asserts that the decision conflicts with a prior Seventh Circuit decision, *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387 (7th Cir. 2010). Pet. 36-37. But intracircuit disagreements do not warrant this Court's review. *See, e.g.*, *Wisniewski v. United States*, 353 U.S. 901, 902 (1957) (per curiam). *Mason*, in any event, does not conflict with the decision below. Quite to the contrary, the court of appeals cited extensively to *Mason* to support its decision. Pet. App. 18-19, 21, 23, 28. The facts and relevant time period in *Mason* were materially different. Mason involved a patient *under the age of 24*, meaning that the patient would have fallen within the scope of the class-wide warnings for pediatric suicide ordered by FDA. *Id.* at 26 n.3 (distinguishing *Mason*). And the suicide at issue occurred before FDA rejected GSK's proposed labeling changes and ordered SSRI manufacturers to remove any adult-suicidality warning for adults over age 24. *Id.*

Petitioner further argues that the court of appeals' decision diverges from decisions of district courts within the Seventh Circuit. Pet. 34-36. Any such conflict would not warrant this Court's review. S. Ct. R. 10. In any event, this contention, too, lacks merit. *Tucker v. SmithKline Beecham Corp.*, 596 F.

Supp. 2d 1225, 1236 (S.D. Ind. 2008) (Hamilton, J.) (Pet. 34-35), predated both *Wyeth* and *Mensing* and, like *Mason*, involved a suicide that occurred years before FDA rejected GSK's proposed labeling changes. Pet. App. 26 n.3 (distinguishing *Tucker*). *Forst v. SmithKline Beecham Corp.*, 639 F. Supp. 2d 948 (E.D. Wis. 2009) (Pet. 35-36), is similarly irrelevant. The suicide attempt in *Forst* occurred in 2004—again, years before 2007. *Id.* at 954. Nor did the district court offer any reasoning for its conclusion that FDA in 2007 "did not preclude Paxil-specific language changes" outside the class-wide warning. *Id.*

III. The Court Need Not Hold this Petition Pending *Merck v. Albrecht*.

This Court need not hold this petition pending this Court's resolution of *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290 (argued January 7, 2019), because the outcome will have no effect on this case.

1. *Albrecht* implicates only one aspect of this case: whether there is clear evidence under *Wyeth* that FDA rejected petitioner's proposed warning. As previously stated, in addition to the "clear evidence" that FDA would have rejected the petitioner's proposed warning, Pet. App. 22-26, after 2007, when FDA mandated a class-wide warning and rejected GSK's proposed modifications to such warning, GSK lacked newly acquired information that would have permitted it to change the label unilaterally, *id.* at 26-28. To be sure, the court of appeals noted that even with its "clear evidence" holding, the CBE regulations permitted GSK to unilaterally change its label had it acquired new evidence of such risks. *Id.* at 26-27. But the point remains that FDA's mandatory class-wide labeling for all SSRIs removed GSK's

adult-suicidality warning, and, as the court of appeals explained, FDA's CBE regulations barred GSK from unilaterally changing this class-wide warning without new evidence. *Id.* The court recognized that this preemption ground was distinct from the "clear evidence" ground, stating that "even if GSK had newly acquired information" it "[could] still succeed" on a preemption defense as long as the evidence is clear that FDA definitely rejected an alleged link between paroxetine and adult suicidality. *Id.* at 20; *cf.* Pet. 34 (arguing that the court of appeals recognized that GSK needed new information from 1992 onward to change its label unilaterally). The decision before the Court in *Albrecht* does not analyze preemption based upon the CBE regulation requiring newly-acquired evidence to change the label unilaterally. Regardless of the outcome, GSK has an independent basis for preemption that is not at issue in *Albrecht*.

2. In any event, even the Court's resolution of the clear evidence question in *Albrecht* will have no impact here. *Albrecht* involves a dispute between the parties as to whether FDA rejected a manufacturer's proposed label because the manufacturer allegedly proposed warning only about relatively benign stress fractures instead of more serious atypical femoral fractures. The Third Circuit held that a reasonable juror could conclude that there was no clear evidence FDA would have rejected a warning about the latter type of injury. *In re Fosamax*, 852 F.3d at 295-300. This Court's resolution of that dispute, however, will not affect the outcome here. The court of appeals here found that the "undisputed evidence" regarding FDA's decision-making was subject to only one reasonable interpretation: FDA, after exhaustively studying the issue for years, definitely and repeatedly rejected an adult-suicidality warning based on

substance and science; indeed, FDA still today requires all SSRI manufacturers, including Paxil's manufacturer, to disclaim any such risk. Pet. App. 9, 22-25.

Petitioner raises three issues, none of which have any merit. *First*, petitioner contends that this case implicates the question of whether *Wyeth*'s "clear evidence" standard is a question of fact for the jury or a question of law for the court. Pet. 27-28. But the court of appeals expressly declined to decide that question, holding that GSK would prevail regardless of the outcome of that question:

> We need not determine in this case whether preemption under *Levine* involves a factual question for the jury. As the Third Circuit noted, "when no reasonable jury applying the clear-evidence standard" could "conclude that the FDA would have approved a label change," then "the manufacturer will be entitled to judgment as a matter of law." *In re Fosamax*, 852 F.3d at 282. That is the case here. … [G]iven the facts in this case, no reasonable jury could find that the FDA would have approved an adult-suicidality warning for Paxil under the CBE regulation between 2007 and Stewart Dolin's suicide in 2010.

Pet. App. 22. This Court's resolution of the fact-versus-law question is thus irrelevant to the *Wyeth* preemption analysis in this case and to whether GSK "waived" its right to "have its preemption defense submitted to the jury." Pet. 27. Even were this Court in *Albrecht* to hold that the Third Circuit correctly held that a jury must assess "why the FDA rejected

[a] proposed warning," Pet. i (No. 17-290), the Court's decision would not alter the result below.[2]

Second, petitioner suggests that this Court might articulate *Wyeth*'s "clear evidence" requirement in accordance with the Third Circuit's articulation of the standard as requiring a defendant to show that it is "highly probable" that FDA would have rejected a plaintiff's preferred warning. Pet. 28. But the Third Circuit made clear that its "highly probable" formulation was nothing but a restatement of the "clear evidence" standard already announced in *Wyeth*. *See In re Fosamax*, 852 F.3d at 285-86. The court used the phrase "highly probable" simply because that is how Black's Law Dictionary defines "clear evidence." *Id.* In any event, GSK would prevail under any formulation. The court of appeals held that "[i]t is hard to imagine clearer evidence that … 'the FDA would not have approved a change' to the paroxetine label" and "[n]o reasonable jury could find otherwise." Pet. App. 22-23. Indeed, petitioner does not even argue that the outcome of her case would be different under the Third Circuit's articulation of "clear evidence." *See* Pet. 28. Thus, whether this Court embraces a "highly probable" standard or a lower standard to establish clear evidence, the decision below will stand.

Third, petitioner asserts that the court below reached the wrong outcome in this case, which she claims has a similar "factual pattern" to *Albrecht*, because the decision below failed to draw all reasonable inferences in petitioner's favor and failed to properly consider the evidence presented. Pet. 28-32. As ex-

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[2] Moreover, petitioner joined GSK in arguing in the district court that *Wyeth* preemption is a question of law for the court. Pet. App. 20. Thus, petitioner herself has waived any argument that preemption is a question for the jury.

plained above, these erroneous assertions mischaracterize the Seventh Circuit's decision. *See supra* pp. 10-11. Moreover, *Albrecht* will have no bearing on the requirements of Rule 50 of the Federal Rules of Civil Procedure. As petitioner recognizes, *Albrecht* involves summary judgment under Rule 56.

IV. Petitioner's Claim Fails for Several Other Independent Reasons.

In addition to being preempted on multiple grounds under *Wyeth* and *Mensing*, the claims fail as a matter of law on additional grounds. Each of these additional grounds is an independent reason to deny review. *See* Stern & Gressman, *Supreme Court Practice* 362 (10th ed. 2013) (citing dismissals as improvidently granted where the judgment was "clearly correct on another ground").

1. GSK did not produce, market, distribute, or profit from the drug Mr. Dolin ingested. Rather, Mr. Dolin took a generic drug manufactured by a generic drug manufacturer. Pet. App. 16. Thus, in order to sue GSK, petitioner "advanced a new theory of liability," coined "innovator liability," under which brand manufacturers could be held liable for "injuries caused by taking generic drugs." *Id*. at 3. Because petitioner's claims were preempted, the court below did not address the viability of petitioner's theory. *Id*. at 29. But such a theory of liability is untenable. Holding brand manufacturers liable for injuries allegedly caused by generic manufacturers would upend tort principles, deter medical innovation, and require brand manufacturers to insure an entire industry when their patents have long since expired and they no longer profit from the drug.

For these reasons, an "overwhelming national consensus" has rejected innovator liability. *Guarino*

v. Wyeth, LLC, 719 F.3d 1245, 1252 (11th Cir. 2013). Seven federal courts of appeals have considered innovator liability under the laws of 24 states, rejecting that theory every time.[3] Overall, more than 100 state and federal decisions have rejected innovator liability under the laws of 29 states. D. Ct. Dkt. 561-23 (Apr. 16, 2017) (collecting cases through August 2016); *but see T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 29 (Cal. 2017); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1219-20 (Mass. 2018) (recognizing innovator liability based on "reckless" conduct). And federal courts, in particular, may not expand state tort law. *See Todd v. Societe BIC, S.A.*, 21 F.3d 1402, 1412 (7th Cir. 1994) (en banc); *Dayton v. Peck, Stow & Wilcox Co.*, 739 F.2d 690, 694 (1st Cir. 1984); *A.W. Huss Co. v. Cont'l Cas. Co.*, 735 F.2d 246, 253 (7th Cir. 1984); *Rhynes v. Branick Mfg. Corp.*, 629 F.2d 409, 410 (5th Cir. 1980).

Petitioner brought her tort claims under Illinois law, Pet. App. 4, 29, and under ordinary Illinois tort principles, manufacturers owe a duty only to their own customers. *See Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 340-44 (Ill. 1990). For this reason, the Sixth Circuit, applying Illinois law, has rejected peti-

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[3] *See Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 168, 170 (4th Cir. 1994); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476-78 (5th Cir. 2014) (per curiam); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 183-84 (5th Cir. 2012); *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 941-54 (6th Cir. 2014); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092-94 (8th Cir. 2013); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612-14 (8th Cir. 2009), *rev'd in part on other grounds sub nom PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Moretti v. Wyeth, Inc.*, 579 F. App'x 563, 565 (9th Cir. 2014); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013); *Guarino*, 719 F.3d at 1252.

tioner's theory. *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 944 (6th Cir. 2014) ("Under Illinois law, a plaintiff must 'identify the supplier of the product and establish a causal connection between the injury and the product.'").

Even if Illinois law recognized innovator liability, that theory would be preempted because it stands as an obstacle to the Hatch-Waxman Act's careful statutory balance between pharmaceutical competition and innovation. Instead of receiving patent and regulatory exclusivities in exchange for easier generic entry, brand manufacturers *also* would have to insure generic sales against state tort claims. Petitioner's theory would take one piece of the Hatch-Waxman regime—generic manufacturers' duty to match brand labels—and hijack it to create market-wide liability Congress never imagined. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348-53 (2001). Indeed, innovator liability could impose costs "large enough … to offset substantially the very benefits Congress intended to confer." *Xerox Corp. v. County of Harris*, 459 U.S. 145, 153 (1982).

2. Petitioner also failed to present evidence from which a reasonable jury could conclude that paroxetine causes suicide in patients over age 24. That should come as no surprise; the absence of such evidence is precisely why FDA prohibited GSK from adding the warning petitioner seeks. Pet. App. 8-9. For example, petitioner's general-causation expert, Dr. David Healy, based his conclusions principally on uncontrolled case reports and relatedness assessments. *See* GSK C.A. Br. 45-50. Federal courts overwhelmingly reject such evidence as "not scientifically valid proof of causation." *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001) (per curiam).

Likewise, even if Paxil could cause suicide in adults over age 24, GSK had no duty to warn under Illinois law because Dr. Sachman, Mr. Dolin's prescribing physician, testified that he independently knew of the purported risk *and* actually warned Mr. Dolin and petitioner about it. GSK C.A. Br. 51-54; *see Proctor v. Davis*, 682 N.E.2d 1203, 1211 (Ill. App. Ct. 1997) ("[T]here is no duty to warn of a risk that is already known by those to be warned."); *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 392 (Ill. 1987) (duty to warn runs to doctor, not patient). The fact that Dr. Sachman specifically warned Mr. Dolin also breaks the chain of causation. *See Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004).

In short, this case should have never been brought. FDA precluded GSK from warning against the risk of suicidality in adults over age 24. GSK did not make the drug that petitioner claims caused her husband's tragic death. And Mr. Dolin and his physician were aware of paroxetine's alleged risks. The court of appeals thus correctly overturned the jury's verdict in this case.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully Submitted,

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