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**

## SUPPLEMENTAL BRIEF FOR RESPONDENT


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## SUPPLEMENTAL BRIEF

This Court's decision in *Merck Sharp & Dohme Corp. v. Albrecht*, No 17-290, provides no reason to grant certiorari or to remand this case to the Seventh Circuit to reconsider its preemption ruling. To the contrary, *Albrecht* confirms that the Seventh Circuit properly applied *Wyeth v. Levine*, 555 U.S. 555 (2009), and *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), when it held that federal law did not permit petitioner's proposed warning because (1) FDA repeatedly rejected petitioner's proposed warning, and (2) GSK lacked newly acquired information that would have permitted it to change the label unilaterally without prior FDA permission.

1. The question decided in *Albrecht*—whether *Wyeth* preemption is a question for a judge or a jury—is irrelevant to the petition and provides no basis for remand. The Seventh Circuit explicitly recognized that this Court had granted certiorari to resolve the judge-vs.-jury issue in *Albrecht* and held below that GSK would prevail regardless of this Court's resolution of that question. Pet. App. 21-22. The court explained that it "need not determine … 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." Pet. App. 22. The fact that the court found preemption under a deferential "no reasonable jury" standard entails *a fortiori* that it would find preemption if it reviewed preemption, as a purely legal question, *de novo*.

The Court also observed that, to find preemption under *Wyeth*, a drug manufacturer must "show [1] that it fully informed the FDA of the justifications for the warning [purportedly] required by state law and

[2] that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." Slip Op. 13. That is precisely the analysis that the court of appeals performed below. The court determined (1) that GSK fully informed FDA of all the data and analyses that could justify an adult-suicidality warning, and (2) that FDA rejected GSK's attempts to add that warning. Pet. App. 22-28. There is no reason to remand this case to the court of appeals for it simply to perform the same analysis and come to the same conclusion.

*First*, the Seventh Circuit held there was no factual dispute that GSK "fully informed the FDA of the justifications" (Slip. Op. 13) for an adult-suicidality warning by submitting to FDA all of the relevant analyses and data that supported a potential association between Paxil and adult suicidality. *See* Pet. App. 22-26. Those submissions included GSK's "reanalysis of data on adult suicidality and paroxetine," as well as the "data … on paroxetine" that FDA requested and used to conduct its own comprehensive "analysis of suicide and adults." Pet. App. 11. The court of appeals, moreover, expressly rejected petitioner's argument that GSK "withheld or manipulated data in its submissions to the FDA" because "the undisputed evidence shows that FDA was aware of the nature of the data it received from GSK." Pet. App. 27. FDA had all the information it needed to determine that an adult-suicidality warning for Paxil was unwarranted.

*Second*, the FDA here, by action "taken pursuant to the FDA's congressionally delegated authority," Slip. Op. 15, formally "informed the drug manufacturer that the FDA would not approve changing the drug's label to include [the proposed] warning," Slip Op. 13. The Seventh Circuit held that "GSK has provided *undisputed* evidence that the FDA rejected any

adult-suicidality warning in 2007 when the agency required all SSRIs to adopt the same class-wide warnings." Pet. App. 22 (emphasis added). After GSK unilaterally added a warning about adult suicidality to Paxil's labeling through the CBE process, FDA rejected GSK's changes and directed GSK to revise the labeling to state "verbatim" that "studies did *not* show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24." Pet. App. 12-14 (emphasis added). FDA's rejection of GSK's unilateral change under the CBE regulations was a "formal[] reject[ion]" (Slip Op. 15) authorized under 21 C.F.R. § 314.70(c)(6)-(7). *See* D. Ct. Dkt. 589-23 (Sept. 25, 2017). When FDA "finalized the new class-wide warnings," it specifically "omitted GSK's paroxetine-specific warning," explaining that "'it is critical that the labeling be consistent for all' SSRIs." Pet. App. 15. And FDA warned GSK that "[f]ailure to" implement the class-wide warning "could make your product misbranded." Br. in Opp. 11.

Remand would be an exercise in futility for petitioner and an unnecessary burden for respondent and the court of appeals. There is nothing in *Albrecht* that could conceivably affect the Seventh Circuit's holding that FDA was fully informed of the risk of suicide in adults and, after fully considering the evidence, rejected GSK's attempts to add an adult-suicidality warning. To this day, Paxil's labeling retains the same class-wide language FDA mandated in 2007—the very language petitioner complains of here. Pet. App. 15-16.

2. Remand also would be pointless for another independent reason. There is nothing in *Albrecht* that undermines the Seventh Circuit's holding that GSK lacked any newly acquired evidence that would have allowed it to add an adult-suicidality warning under

the CBE regulation. *See* Pet. App. 26-28. As this Court observed in *Albrecht*, a manufacturer cannot unilaterally change its label without newly acquired evidence. The CBE regulation "permits drug manufacturers to change a label without prior FDA approval" only where "there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm." Slip Op. 3-4 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)). The Seventh Circuit held that in addition to there being "clear evidence that the FDA would have rejected [plaintiff's proposed] warning in 2007," GSK also "lacked new information after 2007 that would have allowed it to add an adult-suicidality warning under the CBE regulation." Pet. App. 20. Accordingly, remand in light of *Albrecht* would serve no purpose.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully Submitted,

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