No. 18-803

In The Supreme Court of the United States

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of STEWART DOLIN, Deceased,

Petitioner,

v.

GLAXOSMITHKLINE, LLC, Formerly Known as SMITHKLINE BEECHAM CORPORATION,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Seventh Circuit

PETITIONER'S RESPONSE TO RESPONDENT'S SUPPLEMENTAL BRIEF

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PETITIONER'S RESPONSE TO RESPONDENT'S SUPPLEMENTAL BRIEF

Petitioner, Wendy B. Dolin ("Dolin"), hereby respectfully responds to the supplemental brief which respondent, GlaxoSmithKline, LLC ("GSK"), served this morning. In its supplemental brief, GSK contends that the Court's recent decision in *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290 ("*Albrecht*") provides no reason to grant certiorari or to remand this case to the Seventh Circuit to reconsider its preemption ruling in light of *Albrecht*. GSK is mistaken.

In *Albrecht*, this Court determined that the question of "pre-emption is one for a judge to decide, not a jury." *Albrecht*, 2019 WL 2166393, at *2 (U.S. May 20, 2019). In addition, and most relevant to the Dolin case, the Court further clarified the "clear evidence" standard which was previously articulated in *Wyeth v. Levine*, 555 U.S. 555 (2009). Specifically, in *Albrecht*, this Court held:

> "'clear evidence' is evidence that shows the court that the drug *manufacturer fully informed* the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning."

Albrecht, 2019 WL 2166393, at *2. *First*, and as outlined in Dolin's petition, Dolin presented substantial evidence that GSK *did not* "fully inform" the FDA concerning the adult suicide risks associated with

paroxetine, as GSK failed to provide to the FDA all the relevant clinical trials related to the issue of adult suicidality. *See* Dolin's Pet. at 12-13; *see also* R.645, Tr.*3354:1-3367:9; and R.646, Tr.*3510:21-24, *3511:21-3512:25. Thus, GSK has not met its demanding defense that it *fully informed* the FDA.

Second, GSK has not presented clear evidence that the FDA "informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." To the contrary, when GSK proposed adding an adult suicide warning (which GSK asked be placed amidst a section of the warning that applied to the entire class of antidepressants involving more than 30 drugs), the FDA informed and indeed *invited* GSK to submit its Paxil specific warning via a separate formal supplement request (i.e., via the formal Changes Being Effected process as proscribed by 21 C.F.R. §314.70(c)). *See* Dolin's Pet. at 15; *see also* App. 100. Certainly, an invitation by the FDA to the manufacturer to submit a proposed labeling change does not constitute clear evidence of non-approval.

Third, if the foregoing were not enough, GSK in its contemporaneous internal discussions concerning this issue, admitted that the FDA never considered much less rejected its adult suicide warning. Specifically, in a June 21, 2007 internal e-mail, GSK summarized its communications with the FDA concerning the Paxil specific suicide warning as follows:

> On June 21, 2007 FDA responded to our CBE submission for [Paxil] (submitted on May 23,

> 2007). . . . **GSK's request of maintaining the Paxil specific language within the class labeling was not addressed. FDA requested that those additions or changes should be addressed with a separate supplement**.

See App. 113-114 (emphasis added). These facts confirm that, under the newly elucidated *Albrecht* standard, GSK has not met its demanding burden of establishing clear evidence of an *irreconcilable* conflict between state and federal law—it has not established that it "fully informed" the FDA of all the data concerning the adult suicide risks associated with Paxil, and has not shown the FDA formally told GSK it would not approve an enhanced Paxil-specific adult suicide warning. Accordingly, at a minimum, and akin to *Albrecht*, the case should be remanded to the Seventh Circuit, to allow the Seventh Circuit an opportunity to reanalyze the case in light of *Albrecht*.

In addition, *Albrecht* held that "the only agency actions that can determine the answer to the preemption question, of course, are agency actions taken pursuant to the FDA's congressionally delegated authority." *Albrecht*, 2019 WL 2166393, at *8. The Court observed that federal law permits the FDA to communicate its disapproval of a warning only by certain specific means, including: (a) via formal notice-and-comment rulemaking setting forth labeling standards; (b) by formally rejecting a warning label that would have been adequate under state law; (c) or with other agency action carrying the force of law. *Id*. In *Albrecht*,

the Court was dealing with a "complete response" letter regarding Merck's proposed Fosamax warning—no such "complete response" was ever issued in the Dolin case. The Court in *Albrecht* did not rule upon whether the purported disapproval "method" at issue in *Albrecht* was within the scope of authority that Congress has delegated to the FDA. Here, GSK's preemption argument (as well as the holding of the Seventh Circuit) rely primarily upon *informal* e-mails exchanged between GSK and the FDA, and the Seventh Circuit never ruled whether these methods of alleged disapproval (and *Dolin*, as outlined in her petition and *supra*, contends there was no disapproval of an adult suicide warning) are within the scope of the authority Congress has lawfully delegated to the FDA.

After clarifying the "clear evidence" standard and confirming that only FDA actions within the scope of the authority Congress has delegated to the FDA would constitute the relevant federal law for purposes of preemption, this Honorable Court remanded the case back to the Third Circuit to reconsider its holding in light of *Albrecht*. *Albrecht*, 2019 WL 2166393 at *10 (" . . . because [Third Circuit] did not have an opportunity to consider fully the standards we have described in Part II of our opinion, we vacate its judgment and remand the case to that court for further proceedings consistent with this opinion."). There is no reason Dolin should not be afforded the same relief here, and thus, she respectfully requests that the Court either grant her petition, or like *Albrecht*, vacate the judgement of the Seventh Circuit and remand her

case back to that Court to address the preemption issues in light of the newly articulated *Albrecht* standards.

Respectfully submitted,

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