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

REPLY BRIEF

BIJAN ESFANDIARI
Counsel of Record
MICHAEL L. BAUM
R. BRENT WISNER
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
(310) 207-3233
besfandiari@baumhedlundlaw.com

DAVID E. RAPOPORT
MATHEW S. SIMS
RAPOPORT LAW OFFICES, P.C.
20 N. Clark, Suite 3500
Chicago, IL 60602
(312) 327-9880

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

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The Seventh Circuit's decision below conflicts with and misconstrues the heightened burden of proof required under *Wyeth v. Levine*, 555 U.S. 555 (2009), fails to take into account the presumption against preemption as mandated by *Levine*, fails to view the evidence in a light most favorable to petitioner as required under Rule 50(a) of the Federal Rules of Civil Procedure, fails to draw all reasonable inferences in petitioner's favor, and its finding of preemption is at odds with nearly every single post-*Levine* district court to examine identical preemption issues involving antidepressants and adult suicide risks,[1] and notably it is at odds with post-*Levine* circuit court decisions involving pharmaceutical drugs, including most importantly, a Third Circuit decision presently before this Court.[2]

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[1] *Forst v. SmithKline Beecham*, 639 F.Supp.2d 948 (E.D. Wis., July 29, 2009) (Paxil); *Aaron v. Wyeth*, 2010 WL 653984 (W.D. Pa. Feb. 19, 2010) (Effexor); *Dorsett v. Sandoz*, 699 F.Supp.2d 1142 (C.D. Cal. March 26, 2010) (Prozac); *Baumgardner v. Wyeth*, 2010 WL 3431671 (E.D. Pa. Aug. 31, 2010) (Effexor); *Schilf v. Eli Lilly*, 2010 WL 3909909 (D. S.D. Sept. 30, 2010) (Cymbalta); *Koho v. Forest*, 17 F.Supp. 1109 (W.D. Wash. 2014) (Celexa); *Muzichuck v. Forest*, 2015 WL 235226 (N.D. W.V. Jan. 16, 2015) (Lexapro); *Cross v. Forest Laboratories*, 102 F.Supp.3d 896 (N.D. Miss. April 6, 2015) (Lexapro); *Shipley v. Forest*, 2015 WL 4199739 (D. Utah July 13, 2015) (Lexapro).

[2] *Merck v. Albrecht*, Case No. 17-290.

I. The Court Should Hold This Petition Pending *Albrecht* as is its Custom

Because this Court is presently adjudicating a similar drug preemption issue in *Albrecht*, Case No. 17-290, the prudent action is to hold this petition and then vacate and remand to the Seventh Circuit for further proceedings in light of *Albrecht*. Respondent, GlaxoSmithKline ("GSK's"), brief in opposition provides no valid justification to deviate from the Court's usual practice of holding petitions for certiorari when a pending case raises identical or similar issues and therefore is likely to affect the decision in the case in which Petitioner seeks certiorari. Indeed, an identical situation occurred when this Court was considering *Levine*. In 2008, while *Levine* was pending with this Court, a petition for a writ of certiorari was filed by two petitioners (claiming certain antidepressant manufacturers had failed to warn of an adult suicide risk) after their cases were dismissed by the Third Circuit on preemption grounds. *Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008), cert. granted, judgment vacated, 556 U.S. 1101, 129 S. Ct. 1578, 173 L. Ed. 2d 672 (2009). The petitioners in *Colacicco*, like Wendy Dolin ("Dolin") in this case, asked the Supreme Court to hold their petition pending the Court's adjudication in *Levine* and then grant the petition, vacate the judgment and remand the matter to the Third Circuit for further consideration in light of the eventual *Levine* decision – which is exactly what this Court ordered. *Colacicco v. Apotex, Inc.*, 556 U.S. 1101 (2009).

The Court heard argument in *Albrecht* on January 7, 2019. The preemption issues raised in *Albrecht* and during oral argument confirm that the Court's determination of the issues in *Albrecht* will no doubt affect, and may well determine, the outcome of this case. There is no reason the Court should not apply to this case the same precedent and procedure of grant, vacate and remand it followed vis-à-vis *Colacicco*, 556 U.S. 1101.

II. Respondent Has Mischaracterized the Record, in an Apparent Effort to Avoid Certification

GSK's opposition brief contains a number of erroneous, misleading and factually unsupported statements that have no relevance to the validity of Dolin's petition for writ of certiorari and are perhaps designed to obscure the relevant issues. Petitioner will not go tit for tat on each misleading and irrelevant issue raised by GSK, however, a few warrant a response. *First*, GSK leads off its opposition by claiming or otherwise implying that Paxil has improved the lives of hundreds of millions of people suffering from anxiety and depression yet the only citation it provides is to the brief written by its lawyers in the Seventh Circuit. *See* Opp. at 2. In fact, there is evidence to the contrary. For instance, according to a 2008 meta-analysis of GSK clinical trials, Paxil was found to be "not superior to placebo in terms of overall treatment effectiveness."

See Corrado Barbui, M.D. et al., *Effectiveness of paroxetine in the treatment of acute major depression in adults: a systematic re-examination of published and unpublished data from randomized trials*, 178 CAN. MED.ASSN.J. 296 (2008) (noting that the clinical trials data suggests that "physicians would need to expose 100 patients to [Paxil] to provide benefit to 11"). The researchers also noted:

> The present analysis, which suggests that paroxetine is associated with a statistically significant increase in the risk of suicidal tendencies, expands the results of previous re-analyses of GlaxoSmithKline's data [citing GSK's 2006 analysis finding a 6.7 times increased risk] . . . **The recently released re-analysis by the US Food and Drug Administration . . . confirmed these figures by showing that, among the selective serotonin reuptake inhibitors and newer antidepressants, only paroxetine was significantly associated with an excess risk of suicidal behavior . . .**

Id., emphasis added. *Second*, GSK states that "FDA conducted its own studies on all SSRIs, including Paxil." Opp. at 3. Not true. The FDA *does not* and *did not* conduct its own studies,[3] rather the FDA reviews and analyzes studies performed by and submitted to the agency by manufacturers. The record confirms that GSK *did not* provide all of the relevant studies to the

[3] *Tucker v. SmithKline Beecham Corp.*, 596 F.Supp.2d 1225, 1234 (S.D. Ind. 2008) ("The FDA does not conduct its own drug trials . . .).

FDA for inclusion in the FDA's analysis. R.645, Tr. *3354:1-3366:17, *3361:18-3362:24, *3366:22-3367:9.

Third, GSK claims that, "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 . . . " Opp. at 4. That is not true. The FDA has *never* required manufacturers to *disclaim* adult suicide risks – to the contrary, the FDA actually asked GSK to submit a formal labeling change pursuant to the Changes Being Effect ("CBE") regulations (21 C.F.R. §314.70) concerning the labeling change, yet GSK refused to do so. App. at 52-55, 100 & 113-115. This likewise ties in to GSK's argument (which the Seventh Circuit erroneously adopted) that on four occasions, FDA purportedly rejected GSK's Paxil-specific adult suicide warnings, yet the record reveals that, during the course of one month via *informal* communications, GSK asked the same incorrect question three to four times (to place its Paxil-specific adult suicide warning in the middle of a class-wide section that applied to all 30+ antidepressant drugs manufactured by different manufacturers) and the FDA eventually simply stated that the proposed Paxil-specific warning did not belong in the class section and instead the FDA stated that GSK should submit a formal supplement (i.e., formal CBE) concerning its Paxil-specific suicide warnings. Thus, it is incorrect to state that the FDA rejected an adult suicide warning four times – rather, GSK informally asked the FDA the same (incorrect) question four times and each time the FDA

informed GSK that it should follow the regulations and submit a CBE pursuant to 21 C.F.R. §314.70. *Id*.[4]

Despite the revisionist story GSK was able to sell to the Seventh Circuit and attempts to sell to this Court, GSK's internal documents presented at trial confirm that GSK understood its Paxil-specific adult-suicide warning was never rejected by the FDA. 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 <u>was not addressed</u>. FDA requested that those additions or changes should be addressed with a separate supplement**.

App. 113-114 (emphasis added). Thus, with respect to the May through June 2007 events, which GSK (and the Seventh Circuit) call "clear evidence" of a warning rejection, GSK contemporaneously admitted that the FDA *had not even addressed* its proposed Paxil-specific suicide warning. The Seventh Circuit then concluded

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[4] Moreover, the only FDA expert to testify at trial, David Ross, M.D. Ph.D., opined at length that the FDA did not reject the Paxil-specific adult suicide warning and that GSK could have and should have utilized the CBE process to issue Paxil-specific suicide warnings at various portions of the label outside of the class label. R.623, Tr.*1147:25-1181:8,*1148:23-1149:9,*1186:5-1211:2,*1212:14-1217:17,*1213:13-17; R.626,*1549:4-7; R.668-16; see also App. 47 & 52-55.

that, under these facts, "no reasonable jury could find that the FDA would have approved an adult suicidality warning for Paxil under the CBE regulation . . . " App. at 22. As an initial matter, the question under *Levine* is not whether the FDA would have approved the Paxil suicide warning, but rather whether GSK presented "clear evidence" that the FDA would have rejected a suicide warning, *Levine*, 555 U.S. at 571. Certainly, that GSK's own employees at the time admitted the FDA had not addressed its Paxil-specific suicide warning and admitted the FDA had asked that GSK submit its Paxil-specific warning via a supplement under the CBE regulations, confirms that there is no evidence, much less clear evidence, that FDA would have rejected a Paxil-specific adult suicide warning (about a risk revealed in a GSK internal meta-analysis of its data). App. 52-55.

Furthermore, GSK's (and the Seventh Circuit's) conclusion that, under these facts, "no reasonable jury" would have found that GSK was permitted to issue a Paxil-specific *adult* suicide warning is contradicted by the fact that nine jurors unanimously found for the petitioner; two separate well-regarded district court judges in this case likewise rejected GSK's preemption defense, *see* App. 63-65 (Zagel, J.) and App. 54-55 (Hart, J.); other district court judges in the Seventh Circuit[5] have likewise rejected identical preemption arguments by GSK, including ironically

[5] *See, e.g.*, *Forst*, 639 F.Supp.2d at 954 (adult Paxil induced suicide); *Mason v. SmithKline Beecham*, 596 F.3d 387 (7th Cir. 2010) (young adult Paxil-induced suicide).

Judge Hamilton, the very author of the Seventh Circuit *Dolin* decision, who reached the exact opposite result in another adult-Paxil suicide case when he was a district court judge. *Tucker*, 596 F.Supp.2d at 1235–36.

III. The Court's Determination of *Albrecht* Will Likely Affect the Analysis and Outcome of this Case

At the heart of the pending *Albrecht* decision is an analysis of what was presented to the FDA, how the FDA responded, and what warning (if any) the FDA rejected as Justice Kagan's questioning during the oral argument in *Albrecht* illustrates:

> And then the whole question boils down to what was your proposal, what was their response, were you both talking about the same things?

See Albrecht Oral Argument Transcript at 6. This is exactly the issue in this case, i.e., when the FDA through informal communications stated that GSK's proposed Paxil-specific adult warning should not go in the middle of the class-labeling section (as that applied to the whole class of drugs), but that GSK should submit a formal CBE supplement that the FDA could review independent of the class-labeling being implemented for over 30 different antidepressants, was the FDA rejecting a Paxil-specific adult warning? Every jury and virtually every jurist (with the exception of the Seventh Circuit panel below) has answered this question in the negative. *See, e.g.*, cases cited at footnote 1, *supra*. Furthermore, whether this factual question should be

answered by a judge or jury is a question likely to be answered by this Court in *Albrecht*. Again, as Justice Kagan noted during the *Albrecht* oral argument:

> My real question for you is suppose we're not at either one of those worlds. Suppose we have an ambiguous letter. Who should decide how to construe it?

See Albrecht Oral Argument Transcript at 30-31. The Third Circuit in *Albrecht* found that this factual question should be adjudicated by the jury. This Court's answer as to the jury vs. court question will impact the Seventh Circuit's decision below. As discussed in the petition, the district court in *Dolin*, which found the Third Circuit's decision persuasive, offered to present this question to the jury, however, GSK refused the district court's offer, *see* App. 35-36. Thus, if it is a factual question, then GSK has waived its defense by rejecting the district court's offer to present it to the jury. Likewise, to the extent this Court in *Albrecht* modifies, clarifies or expands upon the clear "evidence standard" promulgated in *Levine*, then this too will be relevant to the instant case and warrants holding Dolin's petition until *Albrecht* is adjudicated.

IV. GSK's Arguments That Dolin's Claims Are Invalid on Non-Preemption Grounds Are Misplaced and Have Been Squarely Rejected by The District Court Below

Outside of preemption, GSK further argues that the petition should not be granted because GSK claims

that petitioner's claims fail on independent state law grounds. First, while GSK admits it was the author of the Paxil label (including the generic paroxetine Stewart Dolin was prescribed), GSK argues it should not be liable under Illinois common law because it did not sell the generic paroxetine decedent ingested. The district court on multiple occasions rejected GSK's lack of duty argument and held that, under Illinois law, GSK owed a duty of care to Mr. Dolin, which GSK breached. *Dolin v. SmithKline Beecham Corp.*, 62 F.Supp.3d 705, 714-718 (N.D. Ill. 2014) (Zagel, J.); *see also* App. 55 (Hart, J.) (same). The district court's finding of duty as outlined in Judge Zagel's cogent decision is premised upon Illinois common law and consistent with Supreme Court decision from other jurisdictions. *T.H. v. Novartis Pharm. Corp.*, 4 Cal. 5th 145, 165 (2017) (California); *Rafferty v. Merck & Co.*, 479 Mass. 141, 157 (2018) (Massachusetts).

Next, GSK states that "Plaintiff failed to present evidence from which a reasonable jury could conclude that paroxetine causes suicide in patients over age 24." Opp. at 20. To the contrary, Dolin presented an abundance of documentary and testimonial evidence over several weeks and a reasonable jury concluded that paroxetine can cause suicide in patients over age 24, and it did so in this case. Pet. at 21-22 and underlying citations to the record; *see also* App. at 44-49. GSK next leaps to the conclusion that "the absence of such [causation] evidence is precisely why FDA prohibited GSK from adding the warning." Opp. at 20. GSK makes no attempt to support this statement because it cannot –

there is absolutely nothing in the record to support this fanciful statement.

GSK goes on to state that Dolin's causation expert, Dr. David Healy, based his opinions "principally on uncontrolled case reports and relatedness assessments." GSK Brief, p. 20. This is blatantly false, and GSK knows it. App. at 44-49.

GSK also states the physician who prescribed paroxetine to Mr. Dolin knew of the suicide risk (which GSK now denies exists) and even conveyed the risk (that GSK denies exists) to Mr. and Mrs. Dolin. Opp. at 21. Contrary to GSK's arguments, the doctor testified he would not have prescribed the drug to Mr. Dolin had he known it posed a suicide risk in patients Mr. Dolin's age. App. at 43.

V. Independent of *Albrecht*, This Case Provides an Ideal Vehicle to Further Define the Contours of Preemption Analysis

Finally, independent of how the court adjudicates *Albrecht*, this case presents unique issues of substantial importance. First, a question that remained unanswered in *Levine* is whether the preemption issue and the manufacturer's responsibility and rights to make unilateral labeling changes should be governed by the regulations in effect during the time the drug was on the market, or if subsequent regulations (including the 2008 changes to the CBE regulations) should have retroactive effect. *Levine* chose not to decide that issue, *see Levine*, 555 U.S. at 569, yet that issue is presented

in this case as outlined in the petition. In addition, this argument was not waived as the parties extensively relied upon the CBE regulations and *Levine* in their briefings to the Seventh Circuit and in her request for rehearing filed in the Seventh Circuit, Dolin specifically fleshed out this exact issue. *See* 7th Cir. Dkt. No. 65.

Likewise, this case addresses the issue of class-labeling and whether the FDA's imposition of class-labeling on an issue, prohibits a manufacturer from issuing truthful warnings about enhanced life-threatening risks associated with its unique drug that are not reflected in the class-label. To prohibit the manufacturer from issuing such truthful warnings, doctors and patients will be denied the opportunity to make an informed decision about which specific anti-depressant to prescribe/take as they are denied information about unique life-threatening risks associated with one of the drugs within the class of drugs. The sole FDA expert that testified in this case, opined that GSK was free to add its Paxil-specific adult suicide warning in other portions of the Paxil label outside the class-labeling section. *See* footnote 4, *supra*.

Finally, against the backdrop of the First Amendment, it is difficult to see how GSK can argue that the Government can prohibit it from issuing *truthful* life-saving warnings which are based upon statistically significant risks uncovered in GSK's clinical trials. Certainly, the First Amendment protects the dissemination of truthful scientific information and likewise protects patients' rights to receive such life-saving

truthful information – a finding of preemption constitutes a tattering of the protections long guaranteed by the First Amendment. *Thompson v. Western States Medical Center*, 535 U.S. 357, 365 (2002); *Bigelow v. Virginia*, 421 U.S. 809, 822 (1975).

CONCLUSION

The petition should be held pending the Court's decision in *Albrecht*, after which the Court should grant the petition, vacate the judgment below and remand in light of *Albrecht*. In the alternative, the petition should be granted.

Respectfully submitted,

BIJAN ESFANDIARI
Counsel of Record
MICHAEL L. BAUM
R. BRENT WISNER
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
(310) 207-3233
besfandiari@baumhedlundlaw.com

DAVID E. RAPOPORT
MATHEW S. SIMS
RAPOPORT LAW OFFICES, P.C.
20 N. Clark, Suite 3500
Chicago, IL 60602
(312) 327-9880