In the United States Court of Appeals for the Seventh Circuit

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

Plaintiff-Appellee,

v.

GLAXOSMITHKLINE, LLC, Formerly Known as SMITHKLINE BEECHAM CORPORATION,

Defendant-Appellant.

On Appeal from the United States District Court for the Northern District of Illinois
No. 12-cv-6403
Hon. James B. Zagel & Hon. William T. Hart

BRIEF OF PLAINTIFF-APPELLEE

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 17-3030

Short Caption: Dolin v. GSK

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

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(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

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2. Rapoport Law Offices

(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

Attorney's Signature: s/ R. Brent Wisner Date: 02/21/18

Attorney's Printed Name: R. Brent Wisner

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Attorney's Printed Name: Bijan Esfandiari

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Attorney's Signature: s/ David E. Rapoport Date: 02/21/18

Attorney's Printed Name: David E. Rapoport

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Attorney's Printed Name: Matthew S. Sims

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JURISDICTIONAL STATEMENT

The appellant's jurisdictional statement is complete and correct.

INTRODUCTION

For nearly thirty years, GlaxoSmithKline, LLC ("GSK") has known the psychotropic drug paroxetine (Paxil) can increase the risk of suicidal behavior in adults. The drug primarily does this by causing a phenomenon called akathisia, a rare but dangerous reaction that causes extreme internal anguish and often outer signs of restlessness—it has been described in the medical literature as "a state worse than death[.]" Tr.*209:9-13.[1] People experiencing akathisia can be driven mad, causing them to commit suicide in violent and unexpected ways. The consequences of this side effect litter the case law: a catholic priest who killed himself;[2] a man who "slashed his wrists with sheet metal, then drilled a chisel bit into his head[.]"[3]; a man who killed his wife, daughter, and granddaughter before taking his own life[4]; a 23-year-

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[1] All citations to "Tr." refer to trial transcripts, located on the record between R.615-655. The pin cites, denoted with *, are the sequential pagination of the overall trial transcripts.

[2] *Tucker v. SmithKline Beecham Corp. ("Tucker II")*, 701 F. Supp. 2d 1040, 1042 (S.D. Ind. 2010).

[3] *Forst v. SmithKline Beecham Corp. ("Forst II")*, 602 F. Supp. 2d 960, 963 (E.D. Wis. 2009).

[4] *Estates of Tobin by Tobin v. Smithkline Beecham Pharm.*, 164 F. Supp. 2d 1278, 1280 (D. Wyo. 2001) (this matter went to trial and the jury returned a verdict against GSK).

old college student who ingested cyanide[5]; and, here, a successful attorney—debt free and financially secure—with a strong 30-year marriage to his high school sweetheart, who impulsively left work, mid-day, and jumped in front of an L train. A1-2, A32. Paroxetine, without proper warnings, is dangerous. People who experience suicidal thoughts while taking paroxetine have no idea it could be caused by the very drug that is supposed to treat their psychiatric condition. And, despite GSK's awareness of the risk, even before the drug was ever approved by the U.S. Food and Drug Administration ("FDA"), GSK never warned the medical community of it.

Here, after five weeks of trial, including testimony from six different medical experts, a jury found GSK liable for its failure to disclose the adult suicide risk in the paroxetine labeling, concluding GSK's negligence in controlling the paroxetine label proximately caused Stewart Dolin's death.

Now, GSK asks this Court to overturn that verdict and create blanket immunity for its wrongful conduct. These arguments, addressed throughout this brief, are unavailing. As the judge who oversaw the five-week trial explained: "GSK's history of misconduct with this drug by failing to warn and providing false information to consumers and the FDA are factors which militate against providing label immunity[.]" A51. This conduct is *exactly*

[5] *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 390 (7th Cir. 2010).

what Illinois common law and federal regulation seek to prevent. And yet, GSK would have this Court believe that neither allows GSK to be held liable. This is absurd, and as the various arguments are unpacked below, it becomes clear that this appeal is nothing more than a continued strategy by GSK to disavow its responsibility, enshrined in both Illinois and federal law, to do right by consumers and warn of serious risks associated with paroxetine.

The jury's verdict should stand, and this Court should affirm the district court's judgment.

REQUEST FOR ORAL ARGUMENT

This appeal raises serious and important issues, potentially affecting the ability of eighty percent of Illinois residents—the percent of the market occupied by generics, *see* GSK.Br. at 22—to pursue claims involving label negligence. Oral argument would significantly aid resolution of this appeal.

STATEMENT OF ISSUES

1. Did GSK prove impossibility preemption by providing *clear evidence* that the FDA would have rejected an adult suicidality warning on the paroxetine label, as required under *Wyeth v. Levine*, 555 U.S. 555 (2009)?

2. Did GSK owe a common law duty under Illinois law to provide an adequate warning to Mr. Dolin's physician about the risk of adult suicide on the drug label that federal law gave it the exclusive right and obligation to control? And, if so, does Illinois law provide immunity for breaching that duty

simply because the pill Mr. Dolin ingested was manufactured by someone else?

3. Did the jury have a sufficient evidentiary basis to conclude that paroxetine can induce adult suicidality and that the paroxetine label was a cause of Mr. Dolin's death?

STATEMENT OF THE CASE

I. Brand Name Manufacturers, Not Generics, Are Responsible for the Content and Accuracy of the Drug's Label as Long as the Drug Remains on the Market

The Food, Drug, and Cosmetic Act ("FDCA") requires drug makers to prove that a drug is safe according to its proposed labeling. *Levine*, 555 U.S. at 567. To obtain approval, the drug manufacturer first submits a New Drug Application ("NDA") to the FDA, which contains a proposed label. *Guilbeau v. Pfizer Inc.*, 880 F.3d 304, 307 (7th Cir. 2018). "The FDA's approval is then conditioned on the manufacturer's use of the label it suggests." *Mason*, 596 F.3d at 391. While the FDA can request changes to a label, ultimately the NDA holder "bears responsibility for the content of its label *at all times*. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long *as the drug is on the market*." *Levine*, 555 U.S. at 570-71 (emphasis added); *accord PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011). Under the FDCA, "[t]he labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious

hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.80(e). The NDA holder has the ability to change a drug label, without prior FDA approval, using the changes being effected ("CBE") regulation, which allows it to add or strengthen warning labels based on new information and/or reanalysis of previously submitted data. *Mason*, 596 F.3d at 392; *Levine*, 555 U.S. at 569. Put simply, federal law charges NDA applicants like GSK with the responsibility of both crafting an adequate label and ensuring its warnings remain adequate.

In 1984, Congress amended the FDCA to increase the availability of generic drugs (the "Hatch-Waxman Amendments") by creating an expedited approval process using an Abbreviated NDA ("ANDA"). *Guilbeau*, 880 F.3d at 307. Once a brand loses exclusivity, generic makers can submit ANDAs to sell generic versions of the drug. The ANDA is approved provided "the drug in question has the same active ingredients, effects, and labeling as a predecessor drug that the FDA has already approved." *Id.*; *see Mensing*, 564 U.S. at 612. Thus, the Congressionally-contemplated ANDA process ensures the NDA holder, not any ANDA sponsor, remains responsible for the accuracy of the label. Once the ANDA is approved, the generic manufacturer only has a duty of sameness. *Guilbeau*, 880 F.3d at 311-12 (quoting *Mensing*, 564 U.S. at 613). In turn, NDA holders are compensated by receiving a "monopoly beyond the expiration of the drug's patent" and an extended "patent by a

period equal to the distribution time lost during the FDA's premarketing testing and approval process." *Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 139 (3d Cir. 1987) (citing 35 U.S.C. § 156).

"[T]he federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers." *Mensing*, 564 U.S. at 626. Unlike an NDA holder, who bears responsibility for the accuracy of the label at all times and is allowed (and indeed obligated when called for) to make changes to a drug label without FDA approval, an ANDA holder is prohibited from changing the label on its own. *Id.* at 624. The law places the duty of label accuracy on the party best equipped to warn, that is, the party that not only developed the original compound but has monitored it during the period of exclusivity.

II. GSK Has Known that Paroxetine Increases the Risk of Adult Suicidal Behavior for Nearly Thirty Years but Never Warned

Paroxetine is a psychotropic drug known as a Selective Serotonin Reuptake Inhibitor ("SSRI"), marketed under the brand name Paxil. A36. The FDA approved it in 1992. A36.

From the beginning, GSK had data demonstrating that paroxetine increases the risk of adult suicidal behavior, i.e., suicides and suicide attempts. Paroxetine induces suicidal behavior through a combination of akathisia, emotional blunting, and decompensation. *See* Tr.*207:12-215:25,

*223:8-224:7, *227:6-228:14, *233:4-244:25.

Akathisia is a psychological (inner) and physiological (outer) phenomenon, induced by drugs like paroxetine. "People have described it like a state worse than death. … I want to jump out of my skin … if you get it, is one of the worst experiences of your life." Tr.*209:9-13. Externally, akathisia can ebb and flow, presenting as nothing one moment and then as an inability to sit still, pacing, nervousness, and agitation the next. Tr.*208:10-212:14, *2044:21-2048:9. Internally, akathisia is "a state of emotional turmoil … people who might never have thought about harming themselves or harming others or doing anything strange or violent are plagued with thoughts they have never had before." Tr.*212:15-213:20; *see* Tr.*2046:7-2047:5. Emotional blunting is psychological numbing, where a person loses the ability to consider the emotional consequences of their actions. Tr.*233:4-235:11. Decompensation refers to a psychotic break. Tr.*238:15-239:12. Any of these phenomena can lead to suicidal behavior, but in combination, they are even more deadly. Tr.*235:3-236:23. There is scientific consensus that these phenomena, akathisia in particular, can lead to suicide. Tr.*2300:25-2302:18, *4136:17-19; A36.

A. Original Paroxetine Data Showed a Nine-Fold Increased Risk of Suicidal Behavior but GSK Incorrectly Presented the Data to the FDA and Never Warned on the Label

In October 1990, Harvard psychiatrists published an article documenting

the emergence of suicidal behavior following initiation of SSRI treatment. R.668-3. As a result of this article, GSK submitted a report to the FDA regarding completed suicides and suicide attempts. R.668-17 at 7-8. In the report, GSK inflated the number of suicide and suicide attempts in the placebo group by improperly counting events that occurred in the "run-in" period—the period where all patients are given placebo pills to wash out other drugs in their system *before* entering the study. Tr.*362:21-265:9. Counting events during the run-in period is scientifically "illegitimate." R.555-1 at *210:11-22; Tr.*956:18-23. Increasing the number of events in the placebo group hid the elevated rates in the paroxetine arm. Tr.*474:8-476:8, *505:6-20, *956:24-957:17, *996:9-997:3. When the events are properly counted, the data shows, among already-depressed patients, a statistically-significant *9-fold* increase in the risk of suicide when taking paroxetine. Tr.*963:20-964:7, *996:9-997:3. Unfortunately, the FDA reviewer copied GSK's faulty suicide numbers into his final report. R.589-36 at 30; Tr.*507:5-510:23.

In 1992, the FDA approved paroxetine and GSK's proposed labeling did not warn about a suicide risk with paroxetine. R.668-12 at 1-2; Tr.*994:1-21, *995:4-998:11. Rather, the label stated that "[t]he possibility of a suicide attempt is inherent in depression[.]" R.668-12 at 2. This "precaution" only linked the suicide risk to the underlying disease (depression) and did not

warn that paroxetine (the drug) could increase the risk.

In 1995, GSK published an article using the same faulty run-in numbers, claiming paroxetine *reduced* the risk of suicidal thoughts. R.590-3. GSK then used the publication "with physicians to alleviate any concerns they may have regarding suicidal ideation." R.668-18 at 2. By this point, GSK was no longer just concealing the nine-fold risk, but affirmatively spreading a narrative to physicians that paroxetine was protective against suicide.

B. Internally, GSK Acknowledges the Incorrect Suicide Data, But Continues to Mislead the FDA and Public

In 1999, a GSK researcher not involved in the original data tabulation, noticed GSK was improperly counting run-in suicides and that the data showed a risk. R.668-29 at 1. This prompted a GSK executive to concede that the data "seems to be ... suggesting that Paxil is associated with a higher rate of suicide vs. placebo." R.668-20 at 1. The next day, a GSK regulatory official reached out to the FDA and asked, "hypothetically" whether it would be appropriate to count suicides during the run-in period. R.668-21 at 1-2. Not surprisingly, the FDA "clearly stated that such a patient should not be counted in our analysis[.]" *Id.* Notwithstanding this response, GSK chose not to take any steps to update its analysis or labeling.

In June 2001, a federal jury returned a $6 million verdict against GSK, finding that paroxetine caused a man to kill his family and then commit

suicide. *Tobin*, 164 F. Supp. 2d at 1280. The verdict prompted concern within GSK: "These suicide reports seem to be appearing too often for comfort ... This is potentially an area in which competitors are likely to capitalise on once the lawyers have finished their work in the courts. It would therefore be prudent to have a publication ready." R.668-4 at 1.

In April 2002, thirteen years *after* the original NDA submission, GSK reached out to the FDA, stating that, "subsequent to ongoing defense of Paxil cases, the issue of attempts in patients on placebo during placebo run-in had been debated" and promised to submit a new analysis. R.668-23 at 1. GSK falsely "assured" the FDA "that this was only an issue in terms of attempts and the other analysis stood as submitted in the NDA and the 1991 report based on the NDA (specifically completed suicides …)." *Id.*

C. FDA Learns About "Emotional Lability" Coding Maneuvers, Prompting an Investigation into Suicide for All SSRIs

In June 2003, FDA was reviewing pediatric data related to paroxetine and learned that GSK was using the term "Emotional Lability" to code certain adverse events "and almost all of these events related to suicidality." R.668-7 at 1-2. Because of this discovery, the FDA decided to "look at the NDAs for the other SSRIs to see whether or not similar events are being hidden by various *inappropriate coding maneuvers*[.]" *Id.* (emphasis added); *see* R.589-14 at 6-7.

In 2004, the FDA reviewed the pediatric data for all SSRIs and concluded, on a class-wide basis, that SSRIs can cause pediatric suicidality. R.589-14 at 7. Then, the FDA requested placebo-controlled data from all antidepressant NDA holders related to adult suicidality. *Id.* GSK submitted its data in March 2006. R.589-20 a 1-3. However, GSK only submitted data in its central database; it did not include placebo-controlled suicide data from locally-funded paroxetine trials. Tr.*3361:18-3362:24, *3366:22-3367:9. Indeed, a GSK physician noted that "GSK have data from additional studies, locally run, that are not on our central database but meet the FDA's criteria for studies that qualify for the suicidality analysis." Tr.*3354:1-3366:17. However, despite this concern, GSK never collected the data from the locally-funded studies and never submitted it to the FDA. Tr.*3361:18-3362:24, *3366:22-3367:9. This omission was important. In GSK's 2006 submission, it reported *one* suicide in patients taking paroxetine. Tr.*3512:5-21. But, GSK was aware of multiple suicides in placebo-controlled, locally-funded, clinical trials. Tr.*3362:8-21; *3510:21-24, *3511:21-3512:25.

D. GSK Internal Suicidality Analysis Shows a 6.7-Fold Elevated Risk for Adults and It Causes GSK to Change the Label

While GSK's incomplete adult suicidality data was being reviewed by the FDA, GSK conducted its own analysis of the data and concluded that paroxetine was associated with a statistically-significant 6.7-fold increased

risk of suicidal behavior in depressed adults of all ages. R.589-20 at 2; R.589-21 at 4. GSK, without any prior FDA approval, added this data to the paroxetine label using the CBE. R.589-21 at 1; R.589-22 at 2. GSK made these changes, in 2006, notwithstanding the existence of generic competition and an apparent drop of over 91% in profits. *See* GSK.Br. at 6.

E. FDA's Analysis Shows a 2.7-Fold Elevated Suicidal Behavior Risk for Paroxetine in Adults over Twenty-Four

After GSK changed the paroxetine label, the FDA issued the results of its adult suicidality analysis for all antidepressants, using, in part, the incomplete data submitted by GSK. *See* R.589-14 at 7. The analysis did not show an elevated risk for suicidality for the class of SSRIs in adults over twenty-four, but for paroxetine, it did show a statistically significant 2.76-times elevated risk for suicidal behavior. *Id.* at 26. This statistically-significant result encompassed all psychiatric disorders and distinguished paroxetine from the other drugs in the SSRI class.

The FDA subsequently issued a class-wide warning for all antidepressant drugs, warning of a suicide risk in children, adolescents, and young adults (under twenty-four), but indicating that the risk did not extend beyond the age of twenty-four. Tr.*1126:16-1137:25; R.589-1 at 1-44. And, while this language may be accurate for SSRIs generally, it is not accurate for paroxetine specifically. *Id.*; *see* R.668-15 at 1-44; Tr.*1138:1-1223:23.

F. GSK Removes Paroxetine-Specific Warning Language from the Label and Declines FDA's Invitation to Discuss Placing that Language Elsewhere in the Label

In May 2007, GSK proposed inserting the 2006 paroxetine-specific language in the middle of the class-wide warning. R.589-27 at 1-2; Tr.*3374:16-3376:4. In response, on June 22, 2007, the FDA told GSK that "we do not believe that your product specific analysis should be included in the class labeling revisions[.]" R.589-30 at 1. The FDA told GSK "[i]f you would like to discuss this matter further, please submit a formal meeting request." *Id.* GSK never took the meeting and never proposed inserting the paroxetine-specific language into another portion of the label. Tr.*3374:6-3376:10, *3375:25-3376:4, *3379:1-20, *3510:25-3511:13. Instead, the label that omitted any warning of the risk of adult suicide remained in place.

III. GSK's Failure to Disclose the Adult Suicide Risk on the Paroxetine Label Caused Mr. Dolin's Death

Stewart Dolin, a Senior Partner at Reed Smith, was experiencing work-related anxiety in June 2010. Tr.*1796:8-12. His doctor and close friend, Martin Sachman, M.D., prescribed him sertraline (Zoloft). Tr.*1690:7-23. Mr. Dolin, however, did not feel well, so Dr. Sachman instructed Mr. Dolin to stop sertraline and transition to Paxil. *Id.* Mr. Dolin's druggist, however, filled his prescription with generic paroxetine. Tr.*1668:16-25, *1711:23-1712:4; A32.

At trial, Dr. Sachman testified: (1) he relied on the 2010 paroxetine label

in deciding to prescribe paroxetine to Mr. Dolin in 2010; (2) the 2010 label did not warn that paroxetine could induce suicidal behavior in adults over twenty-four; (3) the 2010 label indicated the risk did not extend beyond age twenty-four and he relied on that representation; and (4) had GSK warned of the risk of adult suicidal behavior over the age twenty-four, he would not have prescribed paroxetine to Mr. Dolin. Tr.*1681:19-1682:10; *1683:25-1684:4, *1761:5-10, *1833:1-19, *1836:7-18, *1836:25-1837:7, *1840:12-16, *1846:24-1847:9, *1848:4-15, *1849:8-14. Dr. Sachman was subjected to vigorous cross-examination. The jury was in the best position to weigh and evaluate this testimony.

Mr. Dolin started paroxetine on Saturday, July 10, 2010. Tr.*1960:19-21, *2609:24-2610:4; *3706:7-10. Shortly after, Mr. Dolin deteriorated. Tr.*1977:13-1978:25, *1980:14-2008:14. For example, a week before starting paroxetine, Mr. Dolin denied any thoughts or inclinations of suicide during a psychological screening. R.589-10 at 9, 11-13. However, two days after initiating paroxetine, he voiced, for the first time, "passive suicidal thoughts" and, according to his therapist, Mr. Dolin changed. *Id.* at 5; R.555-7 at *174:23-175:17. Similarly, on July 14, 2010, the evening before his death, Mr. Dolin participated in an emergency therapy session with another therapist, where he again expressed suicidal thoughts. R.555-6 at *246:19-23, *270:5-171:17, *298:21-299:17, *285:18-287:17. Unlike any time before, Mr. Dolin's

anxiety did not abate during the session. *Id.* This elevated anxiety prompted the therapist to call Mr. Dolin the morning before his death and advise him to get a fast-acting sedative. *Id.*

Mr. Dolin showed similar signs of deterioration at work and home. Mr. Dolin's law partner testified that Mr. Dolin was having difficulty thinking through simple legal issues and that, in his opinion, the stresses of work that week were nothing unusual. Tr.*2399:25-2400:13, *2404:14-2406:1. Similarly, one of Mr. Dolin's clients testified that Mr. Dolin appeared different and unusual after starting paroxetine, unlike ever before. Tr.*1988:9-1991:1. And, Mr. Dolin's wife and daughter observed him pacing around and acting different the week before his death, while on paroxetine. Tr.*2508:15-2509:17, *2542:17-2544:25, *2545:19-2546:20.

On July 15, 2010, Mr. Dolin left his office, proceeded to the Washington Street L train. A nurse witnessed Mr. Dolin on the platform moments before his death. R.555-5 at *40:7-47:13, *47:20-48:4, *48:16-25. Mr. Dolin appeared agitated and extremely anxious, nervously pacing around the platform—consistent with drug-induced akathisia—like a caged "polar bear." *Id.* at *49:22-50:12, *74:7-10. When the O'Hare-bound train pulled into the station, Mr. Dolin jumped in front of the train. *Id.* *51:21-52:6. An autopsy confirmed paroxetine was in his blood. R.668-9 at 1; A44. The jury heard testimony that Mr. Dolin's suicide was the result of an involuntary drug-induced reaction

caused by his ingestion of paroxetine. Tr.*2024:9-21, *2248:24-2251:2.

IV. The Jury Concludes GSK's Negligence in Crafting and Controlling the Paroxetine Label Caused Mr. Dolin's Death

Trial commenced March 14, 2017 and the jury returned a verdict, in favor of Plaintiff, on April 20, 2017. At trial, Plaintiff presented three experts: (1) David Healy, M.D., PhD., a psychiatrist, professor, and neuropsychopharmacologist; (2) David Ross, M.D., Ph.D., an internist, former FDA director, and current Director at the United States Department of Veteran Affairs; and (3) Joseph Glenmullen, M.D., a psychiatrist and clinical instructor at Harvard Medical School. R.341 at 3-4, 6-7, 11. Dr. Healy provided testimony about how paroxetine can induce suicidal behavior in adults. *Id.* at 4-5; A45. Dr. Ross, having worked as a director and medical reviewer at the FDA for ten years, provided testimony about the paroxetine label and GSK's interactions with the FDA. R.341 at 7-9. Dr. Glenmullen provided testimony about whether the paroxetine Mr. Dolin ingested caused his suicide. *Id.* at 11-14; A45.

In addition, Plaintiff presented testimony from (1) numerous GSK company witnesses via videotaped deposition; (2) Mr. Dolin's two therapists; (3) Mr. Dolin's prescribing physician; (4) an eyewitness to Mr. Dolin's death; (5) colleagues who worked closely with Mr. Dolin; and (6) Mr. Dolin's family.

SUMMARY OF ARGUMENT

The jury verdict and district court's judgment should be affirmed.

First, GSK has not and cannot meet its federal preemption burden of providing clear evidence that the FDA would have rejected an adult suicide warning for paroxetine, as required under *Wyeth v. Levine*. Every court within this circuit has rejected GSK's assertion that the FDA would have refused an adult suicide warning in 2007. This case should fair the same.

As a threshold issue, if *Levine's* clear evidence standard is a factual issue to be decided by the factfinder, then GSK has waived its defense by refusing to submit the issue to the jury. If, on the other hand, the Court is the factfinder, then any review of the district court's rulings would be under the "clear error" standard.

On the merits, GSK cannot prove the FDA would have rejected a warning because GSK never actually attempted to put proper warnings in the paroxetine label. GSK refers to language it inserted in 2006, but as explained during trial, those warnings were insufficient. And, without having attempted to insert the warnings required to satisfy Illinois law, GSK cannot then show that the FDA would have rejected those warnings. Moreover, even if the 2006 warnings were enough, that GSK specifically inserted adult suicide language into the label without objection from the FDA and then, in 2007, the FDA specifically invited GSK to discuss keeping that language in the label, undermines any suggestion that the FDA would have rejected a

label change. On this record, GSK falls short of meeting the clear evidence standard.

Second, the jury held that GSK was negligent in its crafting and control of the paroxetine label and that GSK's label proximately caused Dr. Sachman to prescribe paroxetine to Mr. Dolin, leading to this death. That Mr. Dolin ingested a paroxetine pill manufactured by a generic manufacturer is irrelevant. The label that substantially contributed to his death was inaccurate because of GSK's negligence, not the generic manufacturer. GSK takes umbrage with this because GSK did not profit from the paroxetine Mr. Dolin ingested. But, GSK did profit handsomely from the very paroxetine label used to prescribe the drug to Mr. Dolin. Nothing under Illinois law shields GSK from liability in this context.

GSK relies on *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324 (Ill. 1990) to carve out immunity. But *Smith* deals with whether a plaintiff can bring a case without identifying which defendant caused her injury. It is about product identification, not label negligence. It is, as the district court held, inapposite.

GSK also claims that the Hatch-Waxman Amendments preempt label negligence because such liability interferes with the law's purpose and objectives. GSK, however, never raised this argument before the district court, so it is waived here. That said, even on the merits, it loses. The Hatch-

Waxman Amendments specifically contemplate that brand manufacturers control generic labels, and the Supreme Court in *Levine* already rejected the argument that state tort law interferes with that statutory scheme.

Third, GSK claims that, at trial, there was insufficient evidence that (1) paroxetine causes adult suicide and (2) that GSK's failure to warn caused Dr. Sachman to prescribe the drug to Mr. Dolin. GSK makes these arguments by presenting one side of the story, ignoring the mountain of expert testimony and statements from Dr. Sachman, himself, that undermine its position. At trial, the jury was presented with reliable and admissible expert opinion about how paroxetine causes adult suicide and, in particular, caused Mr. Dolin's death. The jury also heard from Dr. Sachman that he was unaware of the suicide risk and that, had GSK warned on its paroxetine label, he would never have prescribed the drug. On this record, the Court should not disturb the verdict.

ARGUMENT

I. GSK Did Not Meet Its Burden in Establishing the Affirmative Defense of Federal Preemption

GSK has raised its preemption defense regarding paroxetine five times within this circuit, and each time it has been rejected. *See Mason*, 596 F.3d at 391; *Tucker v. SmithKline Beecham Corp. ("Tucker I")*, 596 F. Supp. 2d 1225, 1227-35 (S.D. Ind. 2008) (J. Hamilton); *Forst v. Smithkline Beecham Corp.*

("Forst I"), 639 F. Supp. 2d 948, 952-55 (E.D. Wis. 2009) (J. Stadtmueller); A27-28 (J. Zagel); A48-50 (J. Hart). This latest challenge is no different.

A. Preemption Is a Demanding Affirmative Defense

"Federal preemption is an affirmative defense upon which the defendants bear the burden of proof.'" *Fifth Third Bank ex rel. Trust Officer v. CSX Corp.*, 415 F.3d 741, 745 (7th Cir. 2005). The defense begins with "a presumption *against* preemption" and seeks, if at all possible, to give state law its full effect. *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't of Health*, 699 F.3d 962, 984 (7th Cir. 2012) (citing *Levine*, 555 U.S. at 565).

Prior to 2000, prescription drug companies rarely invoked conflict preemption and, "when they did, it rarely succeeded." *Mason*, 596 F.3d at 391 (citing examples). However, in the early 2000s, pharmaceutical companies, aided by the FDA's legal department, began making a flurry of preemption challenges, arguing that state tort law interfered with FDA regulation. *Id.* The question was resolved in the watershed case *Wyeth v. Levine*.

In *Levine*, the plaintiff's arm was amputated after it developed gangrene because a physician's assistant injected her with an anti-nausea drug, Phenergan, using an "IV-push" method. 555 U.S. at 558-59. The plaintiff sued Wyeth claiming it should have warned about the risks of using the IV push method. *Id.* at 559-61. It went to trial and the jury returned a verdict in

plaintiff's favor. *Id.* On appeal, Wyeth argued that plaintiff's state law failure-to-warn and negligence claims were preempted because it was impossible for the manufacturer to comply with the duties imposed by state law and the labeling requirements set forth by the FDCA. *Id.* at 564-65. It also argued a plaintiff should not be permitted to challenge an FDA determination because, to do so, would interfere with the FDA's congressionally-determined mission. *Id.* at 563-64.

The Supreme Court rejected both arguments. *Id.* at 564-81. The Court analyzed the history and purpose of the FDCA and concluded state law was not an obstacle to the FDA's regulation of prescription medication, it was a *complement*. *Id.* at 575-78. The Court examined whether it would be impossible to comply with FDA regulations and the requirements set forth in state tort law and concluded there was no conflict. *Id.* at 568-73. The FDCA allows drug manufacturers to strengthen warning labels as soon as it learns of a risk, whether based on new information or reanalysis of previously submitted information, pursuant to the CBE regulation. *Id.* at 568-71.

The Court did carve out a narrow exception—a state law failure-to-warn claim can be preempted if the manufacturer shows, based on "clear evidence" that the FDA "would have prohibited" the manufacturer from strengthening its warning. *Id.* at 571. Absent evidence of an "affirmative decision … to prohibit [the manufacturer] from strengthening its warning," a failure to

warn claim is not preempted. *Id.* at 572.

In *Mason*, this Court explored *Levine's* "clear evidence" standard in the context of another paroxetine suicide lawsuit. 596 F.3d at 392-93. The Court noted that, in *Levine*, "the record contains ample evidence that the FDA specifically considered and reconsidered the strength of Phenergan's IV-push-related warnings in light of new scientific and medical data" and that "[t]aking *Levine* as a whole, it is clear from the ample administrative record that the FDA strongly considered a similar warning to the one the plaintiff proposed and the Court still did not find preemption." *Id.* at 392-93 (quotation omitted). Absent a more compelling record, preemption is unavailable. *Id.*

B. GSK Either Waived Its Affirmative Defense by Refusing to Submit it the Jury or the District Court's Decisions Are Reviewed for Clear Error

In *Mason*, this Court suggested that preemption was a legal issue, presumably to be decided by the Court. 596 F.3d at 390. But, other courts, addressing this point more directly, have held otherwise. For example, the Third Circuit holds that "the question of whether the FDA would have approved a plaintiff's proposed warning is a question of fact for the jury" reasoning that "[t]he basic question that [*Levine*] poses to a factfinder … requires an evaluative inference about human behavior based on correspondence, agency statements, contemporaneous medical literature,

[and] the requirements of the CBE regulation[.]" *In re Fosamax Prod. Liab. Litig.*, 852 F.3d 268, 293 (3rd Cir. 2017). And, in this case, the district court agreed with *In re Fosamax*, holding that preemption was "a factual question for the jury." A35.

If the preemption affirmative defense should be decided by the jury, then this Court need not consider GSK's preemption arguments on appeal. Judge Hart proposed submitting the issue to the jury. GSK refused. Tr.*4244:17-22, *4244:3-4250:22; A35. Thus, GSK waived it.

If, however, *Levine* preemption is to be decided by the Court, then it must be reviewed under the clear error standard. This is because the "clear evidence" standard under *Levine* is not a pure legal issue; it requires, by definition, a weighing of the facts surrounding interactions with the FDA. *See Levine*, 555 U.S. at 572. As such, the Court must review the district court's findings under a deferential standard. *See Thomas v. Gen. Motors Acceptance Corp.*, 288 F.3d 305, 307-08 (7th Cir. 2002). The Court can only overturn the district court's preemption rulings, and their attendant factual findings, if it finds clear error. *Id.*; *see Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 575 (1985). GSK does not meet that standard.

C. GSK's Preemption Defense Fails Because GSK Has Not Provided Clear Evidence that the FDA Would Have Rejected an Adult Suicidality Warning

1. GSK Incorrectly Assumes the Proposed 2007 Labeling

Would Have Been Sufficient

GSK claims that it attempted to give the warning demanded by Plaintiff, but the FDA rejected it. GSK.Br. at 38-39. This argument assumes that the language GSK proposed in 2007 is the language Plaintiff's experts believe should have been included in the label. But, this is not correct. During trial, Plaintiff's labeling experts disavowed GSK's proposed language as misleading because it suggests the risk of suicidality is limited to people under thirty. Tr.*1124:10-1126:15, *1551:17-1552, *1555:25-1563:6; *see* A48-49. GSK never proposed the warning Plaintiff alleges should have been included in the paroxetine label, i.e., a short plain statement that paroxetine ingestion is associated with suicidality in adults of all ages. Tr.*1128:1-16; A49; *see* Tr.*1138:1-1223:23; R.668-15 at 1-44. Because GSK never attempted to add the warning required by Illinois law, it cannot, now, claim there is clear evidence the FDA would have rejected such a change. *Levine*, 555 U.S. at 572. In other words, GSK's *Levine* defense fails before even getting started.

2. Even if the 2007 Labeling Was Sufficient, GSK's Preemption Defense Fails Because the FDA Never Rejected the Proposed Labeling and GSK Never Proposed a Warning Outside of the Class Labeling

In May 2006, GSK's analysis of the paroxetine-suicide data revealed a statistically significant risk in adults of all ages. R.589-20 at 2; R.589-21 at 1. This prompted GSK, without prior approval from the FDA, to amend the

paroxetine label to include the language at issue. R.589-21 at 1. A year later, on May 2, 2007, FDA notified all antidepressant manufacturers that they would need to implement class wide labeling relating to the suicide risk for young adults, i.e., patients 18-24. R.589-25 at 3. This prompted GSK to informally ask a reviewer for the FDA, via email, whether the class labeling would replace the language GSK added in 2006. *Id.* The FDA reviewer, however, did not directly answer GSK's question, stating that GSK was required to implement the class wide labeling. *Id.* at 1. Then, on May 11, 2007, GSK submitted a formal letter to the FDA inquiring whether the FDA agreed that the 2006 paroxetine-specific language should be included with the class labeling. R.589-27 at 1-2. In response, on May 15, 2007, the FDA, again, did not respond and told GSK to submit a CBE request, at which point the FDA would respond to the request with other proposals from other manufacturers. R.589-28 at 1.

On June 21, 2007, the FDA completed reviewing the companies' submissions and instructed the companies to implement the class wide warnings as originally requested. R.589-29 at 1-2. The next day, an FDA reviewer sent an email to GSK stating: "the Agency has reviewed your proposed changes, and we do not believe that your product specific analysis should be included *in the class labeling … If you would like to discuss this matter further, please submit a formal meeting request.*" R.589-30 at 1

(emphasis added). GSK, however, never took that meeting nor any action to include a paroxetine-specific warning outside the class warning. Tr.*3374:6-3376:10, *3379:1-20, *3510:25-3511:13.

On this record, GSK cannot meet its demanding burden. First, the FDA never considered whether the paroxetine label should include information about paroxetine inducing suicidality in adults over twenty-four and, thus, never *rejected* it. A contemporaneous internal GSK document confirms that the FDA "requested additional changes in the wording of the class labeling" but that "GSK's request of maintaining Paxil specific language within the class labeling *was not addressed*." *Id.* (emphasis added). The document states that "FDA requested that those additions or changes should be addressed with a separate supplement" and that "FDA confirmed that *we would have to ask for a meeting* to discuss the option of including Paxil specific language in the label." *Id.* (emphasis added). On cross-examination, GSK's company witness admitted that the FDA never told GSK that it was "prohibited from putting any Paxil-specific information anywhere in the label." Tr.*3375:16-19.

The district court's conclusion that "it does not appear that there is 'clear evidence' that the FDA would have refused to permit GSK to add a warning of a risk of adult suicide[,]" A49-50, *see also* A28, is not clearly erroneous. Judge Hart and Judge Zagel, having carefully considered the record, made

factual findings, and those findings were supported by considerable evidence. Finding clear error would require this Court to determine that both Judge Hart and Judge Zagel clearly erred in deciding the preemption issues. Such a finding is untenable. And, these two district court judges do not stand alone on this point. Honorable David F. Hamilton rejected this *exact same* preemption challenge ten years ago. *Tucker I*, 596 F. Supp. 2d at 1236.

Second, even if the Court were to conclude that the FDA rejected insertion of the paroxetine-specific language in 2007, that rejection was limited to GSK's very narrow request, i.e., to include the paroxetine-specific language in the middle of the class labeling. *See* Tr.*3374:17-21. GSK's company witness admitted GSK never attempted to propose a warning outside of the class labeling. Tr.*3375:25-3376:4. And, Plaintiff's FDA expert spent considerable time testifying about the various places GSK could have included the paroxetine-specific language outside of the class labeling. Tr.*1147:25-1181:8, *1148:23-1149:9, *1186:5-1211:2, *1212:14-1217:17, *1213:13-17, *1549:4-7.

GSK takes issue with this, arguing that it "is inconceivable" and "insulting" that, if there were truly a risk, the FDA would not have ordered a new label to "protect patients from a life-threatening risk." GSK.Br. at 43. But the FDA was not on trial. *Levine*, 555 U.S. at 575 ("Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety[.]");

The "FDA has limited resources to monitor the 11,000 drugs on the market, [while] manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." *Id.* at 578-79. And, they sometimes make mistakes. Tr.*1549:8-1551:10.

The district court's conclusion that "[t]here is not clear evidence that the FDA would have rejected a Paxil-specific warning outside of the class warning" is not clearly erroneous; indeed, it is eminently reasonable. And, again, the district court does not stand alone. Honorable J. P. Stadtmueller similarly held in rejecting GSK's *Levine* defense:

> [T]he FDA merely required removal of Paxil-specific language from a particular portion of Paxil's label in favor of uniform class-wide labeling for all SSRI's. The agency's action did not preclude Paxil-specific language changes to other areas of the labeling or prevent GSK from pursing a label change through submission of a separate supplement.

Forst I, 639 F. Supp. at 954.

In assessing the "clear evidence" standard, *Levine* is the "intellectual anchor—if the evidence here is less compelling than it was in *Levine*, we will not find preemption[.]" *Mason*, 596 F.3d at 392. The evidence for paroxetine is not more compelling. Indeed, unlike in *Levine*, the record here shows that the FDA specifically invited GSK to discuss inserting into the label the language it claims the FDA would have rejected. *See* A28; A50; *Tucker*, 596 F. Supp. 2d at 1236; *Forst*, 639 F. Supp. at 954. As such, "[o]n the record before

us, [GSK] has failed to demonstrate that it was impossible for it to comply with both federal and state requirements." *Levine*, 555 U.S. at 573.

3. GSK's Remaining Arguments Concerning Preemption Are Also Unavailing

GSK attempts to side-step this record by arguing that GSK did not possess "newly acquired information" that would have allowed it to change the paroxetine label under the CBE after 2007. *See* GSK.Br. at 36-38. But, GSK's actions *after* 2007 are not really at issue—to meet its burden, GSK must show, with clear evidence, that the FDA would have rejected an adult suicidality warning in 2007, during its discussions with the FDA.

Moreover, the Supreme Court has already rejected this "cramped reading" of the CBE regulation: "'newly acquired information' is not limited to new data, but also encompasses 'new analyses of previously submitted data' … The rule accounts for the fact that risk information accumulates over time[.]" *Levine*, 555 U.S. at 569; *see* Tr.*1570:20-23. Nothing prevented GSK, even after 2007, from changing the label to strengthen the paroxetine label based on its reanalysis of the suicide data. *Levine*, 555 U.S. at 570 ("Wyeth could have analyzed the accumulating data and added a stronger warning[.]"); *see* Tr.*1571:7. Indeed, Plaintiff presented evidence that GSK conducted a reanalysis of its suicide data in 2008, showing a statistically significant "ten-fold increase in risk for people aged 25 to 64" for definitive

suicidal behavior. Tr.*1229:18-1234:16, *1624:7-1628:8. That analysis, itself, comprised "newly acquired information."

GSK also argues that, even if GSK had taken the meeting with the FDA, it "does not suggest FDA would have approved plaintiff's warning." GSK.Br. at 43-44. According to GSK, if the mere possibility of changing a label were enough to defeat preemption, it "would be 'all but meaningless." *Id.* at 44 (quoting *Mensing*, 564 U.S. at 621). But, this argument turns the preemption analysis on its head. GSK invokes *impossibility* preemption, which starts with a presumption against it. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 334 (2008). And, that presumption remains until GSK meets its "stringent" burden "of proving that there was clear evidence the FDA would have rejected the proposed change in the drug's label." *Mason*, 596 F.3d at 391. In this context, Plaintiff is *not* required to prove *anything*, let alone that the FDA would have accepted a paroxetine label change. The fact that the FDA specifically invited GSK to discuss placement of paroxetine-specific warnings in the label undermines any suggestion of impossibility. The district court's preemption rulings do not rest on some remote possibility that the FDA would have accepted the label change; it rests on the lack of *clear evidence* the FDA would have *rejected* it.

Finally, GSK argues that if it had warned about the risk of paroxetine-induced suicidality in adults over twenty-four, it would have conflicted with

the class warning language on the label, rendering the drug misbranded. GSK.Br. at 41-42. But this argument mischaracterizes the warnings. The class warning applies to antidepressants generally, not paroxetine specifically, and is based on the FDA's 2007 analysis of all antidepressants. *See* R.589-14 at 26. Paroxetine, however, is unique, and the label's failure to provide paroxetine-specific language is what renders it inadequate. *See* Tr.*1139:17-1140:24, *1131:10-17, *1143:22-1144:8. Including paroxetine-specific language would not conflict with the class labeling.

Under *Levine*, GSK bears the burden to prove the FDA would have rejected an adult suicide warning with clear evidence. The record, as it stands, does not come close to meeting that standard. GSK is not entitled to preemption.

II. GSK Is Responsible for Injuries Caused by Its Negligence in Crafting and Controlling the Paroxetine Label

The jury found GSK negligent for crafting and controlling the paroxetine *label* and that the paroxetine *label* proximately caused Mr. Dolin to be prescribed the paroxetine that led to his death. The jury did not find GSK liable for its conduct in manufacturing the type of drug Mr. Dolin ingested. Notwithstanding, GSK repeatedly attempts to reframe *label* liability into *products* liability—coining the term "innovator liability"—claiming the district court held "GSK liable for injuries allegedly resulting from Dolin's

ingestion of a drug manufactured and marketed by someone else[.]" GSK.Br. at 19. But, that is like pushing someone in front of a bus and claiming it's the bus manufacturer's fault. While it is true this case involves the paroxetine compound, GSK's liability turns on its negligence related to the *creation and control of the paroxetine label*, not the pills. The district court made this point abundantly clear. A10-11; A51. Indeed, the jury was specifically instructed on label liability, *not* product liability. R.571 at 17 (describing Plaintiff's contentions related to the label); *id.* at 18 (describing GSK's duty related to label); *id.* at 20-23 (discussing elements of negligence). Thus, GSK's appeal, focusing on whether it is liable for injuries caused by a product it did not make, seeks reversal of a holding the district court never made.

A. Label Negligence Is Not Products Liability

Nothing in Illinois law requires product manufacturers to be sued exclusively under products liability. In *Board of Education of City of Chicago v. A, C & S, Inc.*, the Illinois Supreme Court held, in a case involving injury caused by an asbestos manufacturer, that "[o]ne who gives false information to another may be liable for physical harm caused by actions taken by that person in justifiable reliance upon the information." 546 N.E.2d 580, 592 (Ill. 1989) (citing Restatement (Second) of Torts § 311 (1965)). The Illinois Supreme Court noted that this type of negligence was broad, "extend[ing] to any defendant 'who, in the course of an activity which is in furtherance of his

own interests, undertakes to give information to another, and knows or should realize that the safety of the person of others may depend upon the accuracy of the information.'" *Id.* (quoting Restatement (Second) of Torts § 311)). And, "the scope of [t]his liability is not determined by the rules that govern liability for the negligent supplying of chattels[.]" *Id.* (quoting Restatement (Second) of Torts § 552, Explanatory Notes, comment a, at 127 (1977)). Thus, it should come as no surprise that, in Illinois, a product manufacturer can be liable for conduct related to negligent statements about their products incidental to manufacturing of the product. After all, "a manufacturer may be liable for injuries to a person not in privity with him and that such liability is governed by the same principles governing *any* action for negligence[.]" *Suvada v. White Motor Co.*, 210 N.E.2d 182, 185 (Ill. 1965) (emphasis added).

Judge Zagel specifically addressed this point, noting that Illinois, unlike states that have enacted specific statutes forcing negligence and products liability claims into the same cause of action, has no such requirement and, indeed, the Illinois Supreme Court has held such a statute to be unconstitutional. *See Best v. Taylor Mach. Works*, 689 N.E.2d 1057, 1105 (Ill. 1997); A7-8. GSK does not explain why Plaintiff's claims must be viewed through the lens of products liability, as opposed to common law negligence. Instead, GSK assumes it, ignoring much, if not all, of district court's opinions.

B. Illinois Common Law Demands, Wherever Possible, a Remedy for Every Wrong

Regarding the claim that was tried, i.e., label negligence, *every* court within the Seventh Circuit that has examined the issue under Illinois law has embraced it. A8-12; *Garner v. Johnson & Johnson, Janssen Research & Dev. LLC*, No. 116CV01494SLDJEH, 2017 WL 6945335, at *7-10 (C.D. Ill. Sept. 6, 2017) (J. Darrow). Indeed, the Seventh Circuit recently endorsed it in a published decision:

> The Hatch-Waxman Act … allows for manufacturers of branded drugs to be *on the hook for mislabeling on their generic counterparts*, precisely because the generic drug manufacturers are prohibited by law from altering the label in any way. In such a case *the branded manufacturer can be said to have "caused" any mislabeling by a generic drug manufacturer, even if the branded drug manufacturer had no hand in the manufacture or distribution of the drug or the labels.*

Pecher v. Owens-Illinois, Inc., 859 F.3d 396, 401 (7th Cir. 2017) (emphasis added, footnote omitted). And, although not binding here, the Court should pay close attention to a recent California Supreme Court decision, *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 21-40 (Cal. 2017), where a unanimous court thoroughly and systematically addressed the issue of label negligence using the same factors and considerations employed under Illinois law.

That fact that courts applying Illinois common law principles have accepted this type of negligence should not be surprising. Illinois negligence law is intentionally broad, based on "the fundamental premise of tort law—

that of just compensation for any loss or injury proximately caused by the tortfeasor." *Clark v. Children's Mem'l Hosp.*, 955 N.E.2d 1065, 1073 (Ill. 2011). Indeed, this principle is enshrined in the Illinois Constitution: "Every person shall find a certain remedy in the laws for all injuries and wrongs which he receives to his person, privacy, property or reputation." Ill. Const. 1870, art. II, § 19.

These guiding principles are important. GSK asks this Court to immunize brand name manufacturers for injuries caused by their labels. Considering generic drugs occupy eighty percent of the market, GSK.Br. at 22, and federal law generally prohibits lawsuits against generic makers, GSK is asking this court to, quite literally, eliminate any remedy for injuries caused in eight percent of the Illinois drug market. It is, put simply, a request to disavow its responsibilities placed squarely on it by federal law. The Court should eschew GSK's invitation to eviscerate the tort rights of millions of Illinois citizens and render impotent the obligations created by the FDCA.

C. Under Illinois Law, GSK Owes a Duty to Those Physicians Who Rely on the Information in the Paroxetine Label to Make Prescribing Decision

To prove common law negligence, Plaintiff must establish "a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by that breach." *Simpkins v. CSX Transp., Inc.*, 965 N.E.2d 1092, 1096 (Ill. 2012) (quoting *Marshall v. Burger King Corp.*, 856

N.E.2d 1048, 1053 (Ill. 2006)). The only issue here is duty, and "[w]hether a duty exists in a particular case is a question of law for the court to decide" *Marshall*, 856 N.E.2d 1048, 1053-54.

Plaintiff asserts, and both Judge Zagel and Judge Hart agreed, that GSK owed a duty to Dr. Sachman (and thus Mr. Dolin) to warn about the risk of suicide on a label over which GSK had exclusive control. The Illinois Supreme Court "has long recognized that 'every person owes a duty of ordinary care to all others to guard against injuries which naturally flow as a reasonably probable and foreseeable consequence of an act, and such a duty does not depend upon contract, privity of interest or the proximity of relationship, *but extends to remote and unknown persons*.'" *Simpkins*, 965 N.E.2d at 1097 (emphasis added) (quoting *Widlowski v. Durkee Foods, Div. of SCM Corp.*, 562 N.E.2d 967, 968 (Ill. 1990)). "[I]f a course of action creates a foreseeable risk of injury, the individual engaged in that course of action has a duty to protect others from such injury." *Id.*

In the pharmaceutical context, "[a] duty to warn exists where there is unequal knowledge, actual or constructive [of a dangerous condition], and the defendant[,] possessed of such knowledge, knows or should know that harm might or could occur if no warning is given.'" *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1123 (Ill. 2002) (quoting *Schellenberg v. Winnetka Park Dist.*, 596 N.E.2d 93, 97 (Ill. App. Ct. 1992)). "A drug manufacturer owes the

medical community the duty to adequately inform them of the risks and dangers of its drugs." *Wingstrom v. Evanston Hosp. Corp.*, No. 90 C 3610, 1992 WL 97934, at *4 (N.D. Ill. May 5, 1992). And, that obligation to warn is not limited to the manufacturer of the pill. For example, in *Happel*, the Illinois Supreme Court held that a pharmacy, possessed of superior information about a drug, owed a duty to warn about that drug, even though the drug was manufactured by another company. 766 N.E.2d at 1124-26.

Here, GSK was charged with a statutory responsibility to maintain the paroxetine label's adequacy and, during that time, GSK possessed superior knowledge about the risks of adult suicide. It seems hardly controversial to conclude that GSK was obliged to protect others from injury flowing from that conduct. Indeed, considering Illinois law does not require privity of interest and specifically contemplates a duty owed to "remote and unknown persons[,]" it is not clear why GSK would owe a duty to those consumers who rely on its labeling and purchase brand name paroxetine, but not those (often the same) consumers who purchase generic paroxetine relying on the same labeling.

In any event, the Illinois Supreme Court has identified four factors that should be weighed in deciding whether to impose a duty: "(1) the reasonable foreseeability of the injury, (2) the likelihood of the injury, (3) the magnitude of the burden of guarding against the injury, and (4) the consequences of

placing that burden on the defendant." *Simpkins*, 965 N.E.2d at 1098. All of these factors weigh in favor of finding a duty.

1. Mr. Dolin's Suicide Was a Reasonably Foreseeable Consequence of Failing to Warn about the Risks of Adult Suicide

"[F]oreseeability of an injury is an important factor in determining whether a duty exists" although not the only one. *Hutchings v. Bauer*, 599 N.E.2d 934, 935 (Ill. 1992); *Simpkins*, 965 N.E.2d at 1099. Here, it was entirely foreseeable that Mr. Dolin's doctor would rely on the representations on the paroxetine label in deciding to prescribe paroxetine to Mr. Dolin and that Mr. Dolin's prescription would ultimately be filled with generic paroxetine. A10; *accord Garner*, 2017 WL 6945335, at *7. Not only do doctors rely on labels to make prescribing decisions—it is, after all, the purpose of a drug label[6]—but GSK controls the label for all versions of the drug. *Mensing*, 564 U.S. at 618. Furthermore, in Illinois, druggists are permitted to substitute generic drugs for brand. *See* 225 Ill. Comp. Stat. Ann. 85/25.

GSK disputes foreseeability by quoting *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 944 (6th Cir. 2014), where the Sixth Circuit disagreed with Judge Zagel's finding of foreseeability. GSK.Br.

[6] 21 C.F.R. § 201.56(a)(1) ("The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug.").

at 29. In *Darvocet*, the court stated "the generic consumers' injuries are not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control" citing a law journal article, authored by three pharmaceutical defense lawyers.[7] That law journal article, however, bases its argument on a Florida state court legal holding[8] that was *specifically* rejected by Supreme Court in *Mensing*. In other words, the article and *Darvocet* analyses are based on abrogated law.

More importantly, it is entirely unclear why a duty is less foreseeable simply because the consequences of a tortfeasor's actions are influenced by a statutory framework. If the consequences of one's actions are dictated by law, then it would make those consequences more, not less, foreseeable. And, it is well-settled that "[d]uties can arise from common law, statute, ordinance, or regulation." *Chiriboga v. Nat'l R.R. Passenger Corp.*, 687 F. Supp. 2d 764, 768 (N.D. Ill. 2009).

GSK claims that "[o]nce exclusivities have expired, brand manufacturers have no say over whether, how, and what extent a generic manufacturer

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[7] Victor E. Schwartz et. al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 FORDHAM L. REV. 1835, 1879 (2013).

[8] *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009) ("No federal statute or FDA regulation imposes a duty or suggests that a name brand manufacturer is responsible for the labeling of competing generic products[.]").

enters the market." GSK.Br. at 29. But, that is irrelevant because GSK had complete control over the label used by those generic manufacturers and, thus, can reasonably foresee the consequences associated with improper labeling.

2. The Likelihood of Someone like Mr. Dolin Committing Suicide Was High Absent a Warning on the Paroxetine Label

GSK does not even attempt to dispute this factor. GSK.Br. at 29-30. Nor could it. Considering GSK's evidence showing paroxetine increases the risk of adult suicide, and GSK's failure to warn of that risk, it was highly likely that a suicide, caused by the drug, would result.

3. The Magnitude of Guarding Against Injury Is Minimal Because GSK's Duty to Warn Exists Regardless of Generic Competition

Under federal law, an NDA holder is required to update and maintain the warning label "as soon as there is reasonable evidence of an association" with risk. 21 C.F.R. § 201.80(e). And, that obligation exists "even if an NDA holder has discontinued marketing a drug product[.]" 78 Fed. Reg. 67985-02 (Nov. 13, 2013) ("These requirements include … proposed revisions to product labeling."); *see* 21 C.F.R. § 314.150(c)). Importantly, that federal obligation is co-extensive with GSK's obligations under Illinois law to warn of "known dangerous propensities." *Martin by Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 354 (Ill. 1996). So, the magnitude of guarding against injury is

the same regardless of whether the consumer is purchasing brand name or generic. Here, "the recognition of a duty to warn would simply require [GSK] to continue with a practice it was already engaged in[.]" *Happel*, 766 N.E.2d at 1124.

GSK confuses the issue, claiming that it would be "difficult to predict what warnings FDA will approve or juries will require[.]" GSK.Br. at 30. But GSK already strikes this balance in complying with its obligations under federal law and in its obligations to Illinois brand consumers. Any burden in guarding against this issue should be no more than the burden GSK already had.

4. Consequences of Placing a Burden on GSK Pales in Comparison to the Benefits Inured by a Protracted Monopoly and the Harm Caused to Illinois Consumers

GSK asserts dire "consequences" of imposing a duty here. Most of these "consequences," however, relate to the costs of compensating for injuries caused by GSK's negligent control of the label. But, costs associated with compensating injuries caused by wrongdoing should not, by itself, be the focus in a duty analysis. The imposition of a duty always increases exposure. If that, by itself, could defeat finding a duty, no court would ever find one.

Moreover, any consideration of "consequences" must be balanced against the fact that GSK can ameliorate that consequence by simply warning. *See Bajwa v. Metro. Life Ins. Co.*, 804 N.E.2d 519, 529 (Ill. 2004) ("Such a burden

would be a modest one compared to the potential for serious injury" by not warning.). GSK has not identified *any* adverse consequences of *complying* with that duty—it has focused, exclusively, on the consequences of being held liable for breaching it.

GSK argues that imposing a duty would make brand name manufacturers insurers for the industry, making GSK potentially liable for the entire generic market while only occupying a small fraction of it. GSK.Br. 21-22. But that is not misleading. Brand-name manufacturers would not be liable for manufacturing defects, *e.g.*, *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 818 (D.S.C. 2011), the failure of a generic manufacturer to update the label to match the brand, *e.g.*, *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584 (6th Cir. 2013), or when a generic manufacturer off-label promotes its drug, *e.g.*, *Arters v. Sandoz Inc.*, 921 F. Supp. 2d 813, 820 (S.D. Ohio 2013). "Under warning label liability, the brand-name drug manufacturer is liable only in a narrow circumstance—when deficiencies in its own label foreseeably and proximately caused injury." *T.H.*, 407 P.3d at 32-33. Imposing a common law duty would only *potentially* create liability in a sub-set of cases (negligent labeling cases) and even then, only after a jury also determined breach, proximate cause, and damages.

Moreover, this whole "insurer" assertion rings hollow because, in 2010, GSK derived income from the sale of generic paroxetine (extended release),

using the *same* paroxetine label, arising from its contractual relationships with Mylan—the very company that manufactured the paroxetine (immediate release) Mr. Dolin ingested. R.656 at 33:5-14. GSK may not have profited from the pill Mr. Dolin ingested, but it was profiting from generic paroxetine at that time. And, that income does not even come close to the billions GSK made during its period of state-sanctioned monopoly.[9]

From a pure public policy perspective, "[t]he public interest in adequate drug warnings … is just as acute when the brand-name drug manufacturer has an effective monopoly over the warning label as it was when the brand-name manufacturer had a monopoly over the entire market for the drug." *T.H.*, 407 P.3d at 34. GSK's claim of being an "insurer" while having certain superficial appeal, misses the important health consequences caused by immunizing the only company with the knowledge and ability to control the label.

GSK also argues that the increased cost of compensating plaintiffs for injuries caused by its negligence would create a chilling effect, deter innovation, and increase prices. GSK.Br. at 22. But, again, that is not necessarily true. Tort liability can spur innovation by incentivizing drug

[9] *See* Alexandra Sifferlin, *Breaking Down GlaxoSmithKline's Billion-Dollar Wrongdoing*, TIME, July 5, 2012, http://healthland.time.com/2012/07/05/breaking-down-glaxosmithklines-billion-dollar-wrongdoing/.

manufacturers to develop new, better drugs. *See T.H.*, 407 P.3d at 34. And, if consumers and health plans start demanding brand name drugs, in lieu of generics, then costs associated with drugs will skyrocket for consumers, health plans, and the government.

More importantly, "accepting [GSK]'s 'chilling effect' argument would be to sanction the *status quo*" where brand name drug manufacturers know of serious health risks "but are under no obligation to follow through with a warning, even where the [brand manufacturer] knows that the drug being prescribed" is without proper warnings. *Happel*, 766 N.E.2d at 1124. And, "the *status quo* is unacceptable" because "[w]here the [brand manufacturer] fails to warn the customer, then the customer is placed at risk of serious injury or death." *Id.*

Consider, for a moment, the consequences of *not* imposing a duty. Finding no common law duty would dis-incentivize GSK (or any other NDA applicant) from ever taking its labeling obligations seriously once it loses exclusivity. After all, GSK pointed out that, within a year of losing exclusivity, only ten percent of the paroxetine market was controlled by GSK, even though GSK exclusively held the obligations to maintain the label. Why would GSK, or any other NDA applicant, ever care about going through the effort of revising the label after losing exclusivity if it only maintained a miniscule portion of the market and could never be held liable for its label?

Imposing a common law duty is not only in line with federal law, it advances the important societal goals of keeping drug manufacturers motivated to update labels when important dangers are discovered.

D. Nothing under Illinois Law Immunizes a Brand Name Drug Company When Its Negligence Proximately Causes Injury

1. *Smith v. Eli Lilly & Co.* Does Not Create Immunity for Label Negligence

GSK's request for label negligence immunity relies heavily on the Illinois Supreme Court's decision *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324 (Ill. 1990). GSK claims that "*Smith* held that a pharmaceutical company cannot be liable for failing to warn about a drug's risks absent proof the company manufactured the particular drug that caused plaintiffs' injury." GSK.Br. at 19. However, a careful reading of *Smith* belies this assertion.

In *Smith*, the plaintiff alleged she sustained injury caused by her mother's ingestion of diethylstilbestrol ("DES") while the plaintiff was in utero. *Id.* at 326. The plaintiff, however, could not identify which company manufactured the DES her mother ingested, so she named 138 different defendants. *Id.* at 326-27. The trial court narrowed the defendants to eight manufactures and dismissed all claims except the plaintiff's strict products liability count, holding that the eight manufacturers could be liable under a market share theory of liability. *Id.*

Market share liability allows a plaintiff to bring claims against a group

of manufacturers that manufactured the product, even when the plaintiff does not know which defendant manufactured the specific product that caused the injury. Liability is apportioned among the manufacturers according to their share of the market. Ultimately, this theory provides an "exception[] to the causation requirement" in tort law by allowing "a plaintiff to shift to a defendant or a group of defendants the burden of proof on the causation issue." *Id.* at 328-29.

When the case made its way to the Illinois Supreme Court, the issue was "whether, in a negligence and strict liability cause of action, Illinois should substitute for the element of causation in fact a theory of market share liability when identification of the manufacturer of the drug that injured the plaintiff is not possible." *Id.* at 325. The Court *specifically* limited its analysis to "the narrow legal issue of whether to adopt market share liability in negligence and strict liability actions[.]" *Id.* at 330. Ultimately, the Court decided not to adopt it.

In the lengthy decision, the Court addresses various aspects of market share liability and, briefly, touches on duty. *Id.* at 343. The plaintiff had argued that drug manufacturers "owe a special duty of care to the public." *Id.* The Court, however, felt such a duty was too broad, and that negligence "require[s] proof that defendant breached a duty owed to a particular plaintiff." *Id.* The Court acknowledged that "[e]ach manufacturer owes a duty

to plaintiffs who will use its drug or be injured by it." *Id.* (emphasis added). But, such a duty requires a connection between the plaintiff and a particular defendant; "the duty is not so broad as to extend to anyone who uses the type of drug manufactured by a defendant … and … does not abrogate the requirement that the plaintiff maintains the responsibility of identifying the defendant who breached the duty." *Id. Smith* does not attempt to set the outer limits of duty for a brand manufacturer for all possible torts.

Smith stands for the unremarkable tort principle that a plaintiff must be able to identify the tortfeasor that caused the alleged injury. And, here, there is no issue over tortfeasor identification or causation. A15. Nowhere in *Smith* does the Illinois Supreme Court address label negligence. In fact, the relationship of the eight *Smith* defendants with DES is nothing like GSK's relationship with paroxetine because, unlike GSK, none of the *Smith* defendants controlled every DES label. The "link" between the plaintiff and a particular defendant that was missing in *Smith*, is present here.

2. *Foster v. American Home Products Corp.* and Its Progeny Are Not Persuasive

GSK claims there is "an overwhelming national consensus" that brand manufacturers owe no duty to warn generic consumers. GSK.Br. at 23. That "consensus" stems from *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994). *Foster* was the first case to consider the issue and, since its

publication, courts have cited to it as persuasive authority. It is the precedential pivot of GSK's argument. It is also a poorly decided opinion that should not bear on this Court's analysis under Illinois law. Indeed, the Fourth Circuit has specifically called the case into question in light of its incorrect interpretation of federal law. *McNair v. Johnson & Johnson*, 694 F. App'x 115, 120 (4th Cir. 2017).

In *Foster*, parents sued a brand name manufacturer when their six-week old daughter died after being given the generic version of a drug. *Id.* at 166-67. On appeal, the court examined whether a plaintiff could maintain a negligent misrepresentation claim against a brand manufacturer under Maryland law. *Id.* at 168. The court's analysis began with noting that a claim for negligent misrepresentation amounted to an attempt to circumvent products liability law and that there was no material difference between the claims. *Id.* Then, the court examined the FDCA and federal drug regulation. *Id.* at 169. The plaintiffs had argued that a brand name manufacturer should be liable for its misrepresentations on the label because the generic label "duplicated the name brand manufacturer's representations[.]" *Id.* But the court rejected this argument reasoning, incorrectly, that generics had independent control over their labels. *Id.* at 169-70.

Turning to duty, the plaintiffs had argued that a duty existed because it was foreseeable "that misrepresentations regarding the [brand drug] could

result in personal injury to users of [the] generic equivalents." *Id.* at 171. But, the court summarily rejected this argument, declaring that "to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far." *Id.* This is, literally, GSK's argument. GSK.Br. at 29.

Foster is rife with missteps and cursory analysis. From the outset, the court would only consider duty in the context of strict products liability. This is evidenced by the court's unsupported declaration that "[t]here is no such relationship between the parties to this case, as [the decedent] was injured by a product that [the brand name manufacturer] did not manufacture." *Id.* at 171. The court did not unpack the central issue of duty, which, under Maryland law, requires an evaluation of several factors, like in Illinois. Moreover, the court's analysis of federal law, finding that a generic manufacturer could unilaterally change the label, was completely wrong. *McNair*, 694 F. App'x at 120.

Since *Foster*, a growing number of courts, including two state supreme courts, have done what the *Foster* court would not—examined a brand name manufacturer's duty in light of foreseeable harm and a proper understanding of federal regulation. And, each court has found a duty, applying nearly identical factors to those used in Illinois. *See T.H.*, 407 P.3d at 27-31 (California); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 658-671 (Ala. 2014) (Alabama); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 705-09 (D. Vt. 2010)

(Vermont); *see also Conte v. Wyeth, Inc.*, 85 Cal.Rptr.3d 299, 311-18 (Cal. Ct. App. 2008) (first case to reject *Foster* under California law); *Garner*, 2017 WL 6945335, at *7-10 (applying Illinois law). The law of Illinois, when properly considered, does not comport with the cursory and invalid reasoning in *Foster*.

E. The Hatch-Waxman Amendments Do Not Preempt Label Liability for Brand Name Drug Companies

GSK argues that any liability for label negligence, here, is preempted by the Hatch-Waxman Amendments. GSK.Br. at 30-36. As a threshold matter, GSK waived this argument by not raising it first with the district court. *See Alioto v. Town of Lisbon*, 651 F.3d 715, 721 (7th Cir. 2011). Despite making numerous preemption challenges, never once did GSK argue that the Hatch-Waxman Amendments preempt label negligence claims. This is entirely new. And, it is "a well-established rule that arguments not raised to the district court are waived on appeal." *Puffer v. Allstate Ins. Co.*, 675 F.3d 709, 718 (7th Cir. 2012).

That said, even if the Court were to consider this new argument, it fails on the merits. GSK asserts "obstacle preemption," a form of conflict preemption that invalidates state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 578 (7th Cir.

2012). In *Levine*, the Supreme Court rejected general obstacle preemption, holding that "Congress did not regard state tort litigation as an obstacle to achieving" the purpose of the FDCA. 555 U.S. at 575, 578-79. Then, in *Mensing*, the Supreme Court clarified:

> [T]he Hatch–Waxman Amendments … allow[] manufacturers to develop generic drugs inexpensively … As a result, brand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. … A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's.

564 U.S. at 612-13. In light of the duties and obligations created by the Hatch-Waxman Amendments, it is difficult to see how imposition of label negligence interferes with anything. The entire premise of label negligence is that brand manufacturers are responsible for the content and accuracy of the label, and that is the *same* duty imposed by the Amendments.

GSK argues that label negligence upsets the careful balance of incentives created by the Hatch-Waxman Amendments. GSK.Br. at 32-33. But, the "balance" brokered by the Amendments pits the length of a brand name manufacturer's monopoly against the desire to increase the availability of generics; it has *nothing* to do with tort liability. And, allowing for label negligence does not upset either side of the equation. *See T.H.*, 407 P.3d at 33 (citing H.R. Rep. No. 98-857, 2d Sess., p. 14 (1984)).

F. Label Negligence Does Not Raise Federalism Concerns

GSK argues that, because "innovator liability is undeniably novel[,]" the district court should have interpreted Illinois negligence law in such way as to restrict liability. GSK.Br. at 27-28. As GSK puts it, any time a federal court is presented with a question of first impression, it *must* side with defendants. This is not the law.

"When faced with a novel question of state law, federal courts sitting in diversity have a range of tools at their disposal" to predict how the state's highest court would rule on the matter. *Pisciotta v. Old Nat. Bancorp*, 499 F.3d 629, 635 (7th Cir. 2007). These tools include "relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand." *Id.* (citing *McKenna v. Ortho Pharm. Corp.*, 622 F.2d 657, 663 (3rd Cir. 1980)). And, even "[i]n the absence of any authority from the relevant state courts, we also shall examine the reasoning of courts in other jurisdictions addressing the same issue and applying their own law for whatever guidance about the probable direction of state law they may provide[.]" *Id.*

And here, the district court did exactly that, relying on, as GSK concedes, "general negligence principles." GSK.Br. at 28. Being liable for a drug label is, itself, not novel. The only issue is whether liability, outside of

the manufacturing process, can attach for failure to warn. And, clearly, it can. *See, e.g.*, *Happel*, 766 N.E.2d at 1124. So, the existence of a duty and whether proximate cause has been established, simply required application of standard Illinois negligence law—a point underscored by the district court using standard Illinois jury instructions. To restrict liability, here, would actually run counter to the Illinois Constitution, which espouses a philosophy of providing a remedy caused by wrongful conduct. *See* Ill. Const. 1870, art. II, § 19; *Clark*, 955 N.E.2d at 1073.

If this Court believes that it should not predict Illinois law, then in light of the fact GSK forced this case into federal court on removal—over Plaintiff's objection, see R.40, 72—and the considerable costs borne by both sides trying this case to verdict, the Court should use its discretion to certify the issue to the Illinois Supreme Court. *See* Cir. R. 52(a); Ill. R. S.Ct. 20(a); *see State Farm Mut. Auto. Ins. Co. v. Pate*, 275 F.3d 666, 672 (7th Cir. 2001). The Fourth Circuit took that approach when it abrogated *Foster* and certified the question to the West Virginia Supreme Court. *McNair*, 694 F. App'x at 120.

III. The Jury's Verdict that Paroxetine Can Cause Suicidal Behavior in Adults and that the Paroxetine Label Proximately Caused Mr. Dolin's Death Is Supported by Sufficient Evidence

"Attacking a jury verdict is a hard row to hoe." *Sheehan v. Donlen Corp.*, 173 F.3d 1039, 1043 (7th Cir. 1999). It is not done "lightly." *Massey v. Blue Cross-Blue Shield of Ill.*, 226 F.3d 922, 925 (7th Cir. 2000). "[T]he jury is the

body best equipped to judge the facts, weigh the evidence, determine credibility, and use its common sense to arrive at a reasoned decision." *Id.* Thus, to overturn a verdict due to insufficiency of evidence "there must have been 'no legally sufficient evidentiary basis for a reasonable jury to find for the non-moving party.'" *Sheehan*, 173 F.3d at 1043 (quoting *Payne v. Milwaukee Cty.*, 146 F.3d 430, 432 (7th Cir. 1998)). The Court's "inquiry 'is limited to whether the evidence presented, combined with all reasonable inferences permissibly drawn therefrom, is sufficient to support the verdict when viewed in the light most favorable to the" Plaintiff. *Id.* (quoting *Emmel v. Coca–Cola Bottling Co. of Chicago*, 95 F.3d 627, 629 (7th Cir. 1996)). Here, GSK attacks two findings by the jury, i.e., that paroxetine can cause adult suicidality and that the paroxetine label caused Mr. Dolin's death.[10] Both fail.

A. The Jury's Conclusion that Paroxetine Can Induce Suicidality in Adults Is Supported by Sufficient Evidence

At trial, Plaintiff presented testimony from three physicians—two psychiatrists (Drs. Healy & Glenmullen) and one internist (Dr. Ross)—who testified that, in their expert opinion, paroxetine ingestion can cause suicidal behavior in adults. Tr.*204:24-205:5, *898:13-20, *902:9-904:7, *2048:10-19.

Prior to testifying, GSK challenged the admissibility of Plaintiffs' experts

[10] Notably, GSK does not challenge specific causation, i.e., whether the paroxetine Mr. Dolin ingested induced his suicide.

under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Judge Zagel, however, rejected those challenges, holding that Plaintiff's experts were "well-credentialed" and provided "well-supported opinions that are relevant and reliable." R.341 at 15. GSK does not appeal this order. *See* R.606 at 1-2. This not surprising considering courts have held that Drs. Healy's and Glenmullen's opinions about paroxetine causing adult suicide are reliable and admissible. *See, e.g.*, *Tucker II*, 701 F. Supp. 2d at 1047-66. So, whether their testimony is reliable or admissible is not at issue; the *only* issue is sufficiency.

Plaintiff's experts' opinions were supported by a host of data. Specifically, the jury was shown an analysis of placebo-controlled Paxil data, conducted by GSK, showing that depressed patients of all ages given paroxetine, as opposed to placebo, were 6.7 times more likely to engage in suicidal behavior and that the results were statistically significant. Tr.*424:7-428:25, *1107:11-1108:22, *1230:22-1232:23. Within that analysis, when the data was restricted to just patients over 25, the data revealed a statistically-significant ten-fold increase in suicidal behavior. Tr.*1627:15-24. Additionally, the jury was shown the FDA's analysis which found a statistically significant 2.76 increased risk for paroxetine across all psychiatric conditions. Tr.*439:22-440:23, *448:5-449:6; *see* R.589-14 at 26. These paroxetine-specific analyses were supported by a number of peer-

reviewed published articles confirming this association. *See* R.590-1 at 9 (discussed Tr.*450:13-454:17); R.590-5 at 5 (discussed Tr.*286:22-295:6); R.590-6 at 1 (discussed Tr.*296:4-301:11). And, the jury was presented with additional peer-reviewed data concerning SSRIs and suicide generally. R.668-3 at 4; R.590-2 at 1-3 (same); R.590-8 at 1.

In addition to the placebo-controlled data, the jury was also shown analyses done on uncontrolled paroxetine data in the 1980s which also showed a statistically significant 9-fold increased risk versus placebo. *See* Tr.*962:6-964:11.

The jury also heard testimony from Dr. Healy about the mechanisms by which Paxil induces suicidal behavior—akathisia, emotional blunting, and decompensation—and how this is a phenomenon he observes in practice. Tr.*207:12-215:25, *223:8-224:7, *227:6-228:14, *233:4-244:25. And, these mechanisms are widely accepted as being associated with suicide. Tr.*2300:25-2302:18; *4136:17-19; *see* A36.

Dr. Healy also discussed other types of data, including clinical observation, health volunteer studies, and challenge, de-challenge, and re-challenge studies. Tr.*306:17-207:11, *308:9-318:12, *323:16-334:25, *355:14-358:6. Dr. Healy tested paroxetine on healthy, non-depressed or suicidal, volunteers, and reviewed similar GSK studies, and he observed the sudden emergence of suicidal tendencies. Tr.*209:20-210:13, *211:10-16, *308:25-

309:9, *310:4-315:3. Dr. Healy discussed challenge, de-challenge, re-challenge data, where depressed patients are given an SSRI and develop suicidality (challenge), are taken off the drug and the suicidality vanishes (de-challenge), and then are re-administered the drug and the suicidality returns (re-challenge). Tr.*323:16-334:25, *355:14-358:6. In fact, GSK's own expert, Dr. Rothschild, specifically published a challenge, de-challenge, re-challenge study involving SSRIs and suicidality. R.590-2 at 1-3.

GSK argues that Dr. Healy based his opinions primarily on case reports and relatedness assessments, and then proceeds to explain why that data is not reliable. GSK.Br. at 47-48. But this is a red herring. Dr. Healy relied on many different types of data supporting his opinion, including statistically significant, placebo-controlled clinical trial data for Paxil. *See* R.341 at 4-5. GSK's attempt to cabin Dr. Healy's opinions to case reports is grossly misleading and not supported by the record.

The question, here, is whether the jury's conclusion that paroxetine may cause adult suicidality finds support in the evidentiary record. And, considering the mountain of testimony and evidence presented by Plaintiff's experts, it does. The verdict should not be disturbed.

B. The Jury's Conclusion that the Paroxetine Label Caused Mr. Dolin's Death Is Supported by Sufficient Evidence

GSK argues that it had no duty to warn Dr. Sachman about the risk of

paroxetine inducing suicidality because, according to GSK, Dr. Sachman already knew paroxetine could induce that risk. GSK.Br. at 51-54. But this is not what Dr. Sachman testified at trial:

> Q. Now, I want to just call your attention to the label that was in effect when -- on June 27th of '10 when you wrote the prescription for Stewart Dolin … Was there any warning in that label that told you that people over 24 were at risk of a drug-induced suicide from Paxil?
>
> A. Absolutely not.
>
> Q. Would you -- if you knew that, would you have ever prescribed Paxil for Mr. Dolin?
>
> A. Absolutely no.
>
> Q. Why not?
>
> A. Because I wouldn't have wanted to risk that ultimate side effect with that drug. There were other choices I could've used.
>
> …
>
> [Q]. Was there anything in the 2010 label that told you, as a doctor, that people above 24 in that label were at an increased risk of suicide attempts?
>
> A. Not at all.

Tr.*1681: 19-1682:10, *1683:25-1684:4; *accord* A40. Then on re-direct, Dr. Sachman testified he relied on the label's representation that the risk did not extend beyond age twenty-four. Tr.*1836:25-1837:7. Dr. Sachman explained: "I'd like to say that in the midst of all of this attempted confusion of the real issue here, *if it was clear that this drug had a higher risk of causing suicide*

in the age group Stewart Dolin was in, I would have never prescribed it." Tr.*1846:24-1847:9 (emphasis added).

GSK focuses on testimony during cross examination where Dr. Sachman was shown portions of the 2010 label dealing with the risks associated with depression and anxiety, not the drug itself, and was asked whether he was aware of that information. *See* GSK.Br. at 52-53 (citing Tr.*1737:13-1740:2, *1751:13-17, *1753:15-1754:2, *1779:17-23). Taking this testimony out-of-context, GSK argues that Dr. Sachman knew paroxetine could induce suicidal behavior in adults over twenty-four. *Id.* This is just a conflation. Dr. Sachman knew suicide was a risk associated with depression and anxiety—as does any physician—but he did not know paroxetine, *itself*, could further increase that risk for adults over twenty-four. Tr.*1843:13-1845:7, *1844:25-1845:7.

This attempt to conflate the risks of the underlying condition with the risks of paroxetine is an old trick for GSK. It tried the same argument in another paroxetine suicide case where it was, rightly, rejected:

> A jury could find that Dr. Todd was not adequately warned about Paxil's increased risk for suicidality and that such information would have affected his prescribing decision. … General awareness that a period of increased suicidality may result from initiating treatment for depression with an antidepressant is different from knowledge that a particular drug may directly increase suicidality.

Forst II, 602 F. Supp. 2d at 968. Like Dr. Todd in *Forst*, Dr. Sachman testified he did not know paroxetine, itself, could induce suicidal behavior in

adults over twenty-four, and GSK's attempt to point to general language associated with depression and the disease's risks of suicide, does not change that fact.

GSK also argues that it sent a "Dear Doctor" letter to Dr. Sachman in 2006 and, thus, he was made aware of the paroxetine suicide risks. *See* GSK.Br. at 55. But, Dr. Sachman specifically testified at trial that he relied on the paroxetine label *from 2010* when he prescribed the drug because that is standard medical practice. Tr.*1761:5-10, *1833:1-19, *1836:7-18, *1837:5-7, *1840:12-16, *1849:8-14. This case is about GSK's failure to warn in 2010, and Dr. Sachman relied on the most up-to-date labeling in making his prescribing decision in 2010—labeling that falsely indicated that the suicide risk did not extend beyond twenty-four. Had the 2010 label warned of the suicide risk, he would never have prescribed the drug to Mr. Dolin.

Ultimately, GSK's challenges to Dr. Sachman's testimony reveal, at worst, inconsistency—testifying at one point that he knew of the suicide risk and at another point that he did not. But, it is not the Court's job to parse what Dr. Sachman really meant. It is well-settled that "the court does not make credibility determinations or weigh the evidence." *Whitehead v. Bond*, 680 F.3d 919, 925 (7th Cir. 2012) (quoting *Schandelmeier-Bartels v. Chicago Park Dist.*, 634 F.3d 372, 376 (7th Cir. 2011)). "Generally, juries may reject parts of a witness's testimony while accepting other parts." *United States v.*

Colston, 936 F.2d 312, 315 (7th Cir. 1991). And here, the jury heard Dr. Sachman's testimony and was asked to decide whether Plaintiff carried her burden. Indeed, GSK spent considerable time arguing its interpretation of Dr. Sachman's testimony to jury at closing. Tr.*4376:4-4387:5. Ultimately, the jury rejected GSK's interpretation and returned a verdict for Plaintiff.

CONCLUSION

The district court's judgment should be affirmed.

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Respectfully submitted,

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CERTIFICATION

This brief complies with the type-volume limitation of Circuit Rule 32(c). The brief contains 13,995 words, excluding those parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface and typestyle requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) and Circuit Rule 32(b) because it was prepared in a proportionately-spaced typeface using Microsoft Word 2016 in Century Schoolbook 13-point font. Enjoy.

s/ R. Brent Wisner
R. Brent Wisner

CERTIFICATE OF FILING AND SERVICE

Pursuant to Federal Rule of Appellate Procedure 25, I hereby certify that on February 21, 2018, I electronically filed the foregoing Brief of Plaintiff-Appellee via ECF, and service was accomplished on counsel of record by that means.

/s/ R. Brent Wisner
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