## IN THE SUPREME COURT OF MISSOURI

## No. SC96151

#### MIASIA BARRON, et al.,

#### Plaintiff/Respondent,

v.

#### ABBOTT LABORATORIES INC.,

## Defendant/Appellant.

## Appeal from the Circuit Court of the City of St. Louis Hon. Steven R. Ohmer

#### SUBSTITUTE REPLY BRIEF OF DEFENDANT/APPELLANT

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# I.Joinder Cannot Create Venue in Contravention of Section 508.010.5 of the2005 Tort Reform Act.

Plaintiff takes the remarkable position that the 2005 Tort Reform Act was intended to expand venue, not contract it. Plaintiff argues the Act was intended to allow out-ofstate plaintiffs injured outside of Missouri to file claims in any Missouri venue so long as they join their claims with a plaintiff injured in that venue. According to Plaintiff, the Act was intended to permit plaintiffs to file suit against corporations anywhere in Missouri, despite the legislature's statement that it was "designed to disallow venueshopping, especially in suits against corporations." As a result, the joinder of a single plaintiff injured in St. Louis City would permit dozens of out-of-state plaintiffs to sue an out-of-state corporation in St. Louis for injuries that occurred across the country.

Plaintiff reaches this remarkable result using a novel interpretation of section 508.010 and its use of the word "action" never before argued in, much less determined by, any court faced with this issue. Plaintiff simultaneously, and strangely, argues that the statute is "plain" but also "silent" with respect to this issue. (Br. 28-35). Plaintiff's interpretive jiu-jitsu supposedly renders legislative history, Supreme Court Rules, and even judicial review irrelevant to the proper analysis of venue.

Plaintiff is wrong. The word "action" does not magically justify a breathtaking expansion of venue by a statute designed to constrain venue and disallow venueshopping. The legislature's intent is not revealed by an entirely new interpretation of an Act passed twelve years ago. Section 508.010 is not "silent as to venue when multiple plaintiffs are properly joined." (Br. 32). "The plaintiff" means *the* plaintiff; it does not mean *any* plaintiff, as Plaintiff would have this Court believe. This Court's Rule 51.01, and its admonition that these "Rules shall not be construed to extend ... the venue of civil actions," should not be ignored. And this Court should not accept Plaintiff's invitation to avoid judicial review, interpretation, and application of section 508.010.5, particularly in light of the drastic consequences that would follow from ignoring what Plaintiff's interpretation has wrought in St. Louis City.

#### A. Section 508.010 Is Not Silent.

Plaintiff grounds much of her argument in the contention that "Section 508.010.4 & .5 are silent as to venue when multiple plaintiffs are properly joined." (Br. 32). Not so. Both subsections clearly state the required venue for when "the plaintiff was first injured in the state of Missouri" and when "the plaintiff was first injured outside the state of Missouri." "The plaintiff" here "was first injured outside the state of Missouri." Thus, venue against this corporate defendant may only be proper in Missouri in the county where the registered agent is located. R.S. Mo. § 508.010.5.

The legislature made this requirement even clearer by noting that both subsections are to be applied "[n]otwithstanding any other provision of law." Plaintiff's suggestion that "section 508.010 permits properly joined plaintiffs to file in either of two statutorilyprescribed venues" (Br. 34) is wrong. These subsections cannot be mixed and matched; that would directly contradict the statute's proscription that the two subsections are to be applied notwithstanding each other. Such an interpretation would render meaningless the venue statute by allowing any plaintiff to sue anywhere. Subsections .4 and .5 cannot both be applied when the legislature specifically stated that each subsection is individually the exclusive mechanism for determining venue for "the plaintiff" notwithstanding the other subsection.<sup>1</sup>

Plaintiff interprets the statute such that subsection .4 applies to the plaintiff "first injured outside the state of Missouri" so long as *any* plaintiff joined in the action "was first injured in the state of Missouri." This interpretation requires two changes to the text of the statute. First, it would require changing the words "the plaintiff" to "any plaintiff." According to Plaintiff, so long as "any plaintiff" in the action was first injured in the state of Missouri. 4 applies to the claim of all plaintiffs joined in the action even if they were first injured outside the state of Missouri. A statutory interpretation that requires the Court to add to or modify the written text of the statute is presumptively wrong. *See Macon County Emergency Svcs. Bd. v. Macon County Comm* 'n, 485 S.W.3d 353, 356 (Mo.banc 2016) ("The court will not add words to a

<sup>1</sup> Plaintiff suggests that section 508.010's application to multiple plaintiff cases is not as clear as House Bill 460, currently pending in the Missouri legislature. (Br. 29). No doubt. The legislature has been forced to use unmistakable language to overrule the Circuit Court's misapplication of section 508.010 and to ensure that it carries out the clear intent of the 2005 Act. The only lack of clarity has arisen from the Circuit Court's refusal to apply the clear language of section 508.010. The statute should be enforced as written and intended.

statute under the auspice of statutory construction.").<sup>2</sup> Second, it would require deleting "notwithstanding any other provision of law," which requires the subsections to be applied to each plaintiff independently of each other.

The word "action" in section 508.010 does not cure the flaw in Plaintiff's argument. Under the statute, "the plaintiff" in the "action" here was "first injured outside the state of Missouri." Section 508.010.5 thus clearly applies. Plaintiff's new argument—made for the first time here and never below—that the word "action" means venue is proper for *all* plaintiffs if it is proper for *any* plaintiff finds no support in the text or legislative history of section 508.010. Plaintiff's argument found no purchase before the passage of the 2005 Act, *see State ex rel. Jinkerson v. Koehr*, 826 S.W.2d 346, 348 (Mo.banc 1992) ("Simply joining the two separate causes of action in a single petition does not create venue over both actions."), and there is no reason to believe the 2005 Act was intended to change this law and allow the use of joinder to create venue in contravention of Rule 51.01. As Plaintiff points out, the General Assembly is presumed to legislate with knowledge of the law. (Br. 39). If the legislature intended to change this Court's law requiring determination of venue for each party regardless of joinder, it

<sup>&</sup>lt;sup>2</sup> Of course, the legislature knows the difference between the use of "the" and the use of "any." Indeed, section 508.010.5 uses both "the" and "any" to modify the same noun in different contexts to produce different meanings ("any county" versus "the county").

surely would have done so by means other than the use of the word "action" in the statute. In reality, the use of the word "action" is entirely consistent with *Jinkerson*.<sup>3</sup>

## **B.** Supreme Court Rule 51.01 Should Not Be Ignored.

For the first 41 pages of her brief, Plaintiff ignores Rule 51.01. No wonder. The rule clearly prohibits precisely what Plaintiff advocates here—using a Supreme Court Rule to extend the venue of civil actions.

When this Court enacted Rule 51.01's prohibition that these "Rules shall not be construed to extend ... the venue of civil actions," the Court did not create an exception for Rule 52.05 on joinder. Yet, that is exactly how Plaintiff contends Section 508.010 should be interpreted—the mere permissive joinder under Rule 52.05 of a plaintiff first injured inside the state of Missouri is enough to extend the venue of the Circuit Court over the claims of plaintiffs who were first injured outside the state of Missouri.

There is no principled difference between what Plaintiff seeks to accomplish here and what this Court ruled against in *State ex rel. Turnbough v. Gaertner*, 589 S.W.2d 290 (Mo.banc 1979). In both cases, multiple claims were joined under Rule 52.05(a). In both cases, plaintiff asserted that venue was proper for multiple claims because it was proper for one. And in both cases, plaintiff relied on Rule 52.05 in an attempt to extend the venue of the circuit court over all claims in the action.

<sup>&</sup>lt;sup>3</sup> If the Court applies both subsections .4 & .5 to this case, it should apply the reasoning of Professor Achtenberg and hold that the first injury of the plaintiffs controls the analysis consistent with R.S. Mo. §1.030.

The result here should be the same. "Venue could not 'be established by means of Rule 52.05(a) when it would not have existed without such joinder." *Id.* at 292. "To hold otherwise would mean that, contrary to the express provisions of Rule 51.01, venue as to [a claim] would be established by means of Rule 52.05(a) when it would not have existed without such joinder." *Id.* Plaintiff cannot avoid the clear holdings of *Turnbough* and its progeny that Rule 51.01 cannot be used to extend venue. *See, e.g., State ex rel. Nixon v. Dally*, 248 S.W.3d 615, 617 (Mo.banc 2008) ("Rule 52.05(a) authorizes joinder of claims ... [i]n cases where venue is proper as to both defendants").

#### C. The Cases on Venue Over Multiple Defendants Do Not Help Plaintiff.

Plaintiff's suggestion that *Turnbough* "is no longer valid law" (Br. 41) is wrong. *State ex rel. Kinsey v. Wilkins*, 394 S.W.3d 446 (Mo. App. 2013), repeatedly reaffirms the core principle of *Turnbough* "that Rule 52.05(a) could not be used to extend venue due to the prohibition prescribed in Rule 51.01." It is true, as Plaintiff suggests, that *Kinsey* held that reliance on the place of the plaintiff's first injury means that venue is proper over two defendants who both injured a single plaintiff based on the location where one defendant first injured the plaintiff. That is because section 508.010 makes clear that the location of the single plaintiff's first injury controls the venue analysis for both defendants. As a result, joinder under Rule 52.05(a) is not the basis for venue against both defendants.

For multiple plaintiffs, however, the location of the first injury for "the plaintiff" is a separate question specific to each plaintiff. As a result, the proper venue for each plaintiff is not identical. Only through joinder under Rule 52.05(a) could Plaintiff attempt to argue that venue over one plaintiff's claim is sufficient to establish venue over all plaintiffs' claims. And that reliance on Rule 52.05(a) is expressly prohibited by Rule 51.01. Just as *Kinsey* undertook a venue analysis for each defendant, this case requires a venue analysis for each plaintiff.<sup>4</sup>

# D. Plaintiff's Interpretation Would Exacerbate the Precise Problem the Legislature Intended to Solve in 2005.

Plaintiff dwells on the purpose of the venue statutes "to provide a convenient, logical and orderly forum for litigation." (Br. 30). Because Abbott is "properly there anyway," according to Plaintiff, Abbott "would have no basis for complaining about venue" with respect to any other claim filed against it. (Br. 38).

In so doing, Plaintiff treats this issue as if it were a discretionary *forum non conveniens* motion. In section 508.010.5, however, the legislature already determined that if an out-of-state plaintiff sues a corporation for an out-of-state injury, then the location of the corporation's registered agent is the only "convenient, logical and orderly forum" in Missouri. Better yet, these cases should be tried where they originated. And if section 508.010.5 were enforced, they would be filed there, not 10 miles away in St. Louis County as Plaintiff disingenuously suggests. Indeed, that is exactly what happened in *Ground v. Abbott Labs., Inc.*, No. 1122-CC08690 (Mo. Cir. Feb. 16, 2015). Once venue evaporated in St. Louis City, the plaintiff voluntarily dismissed and re-filed in his

<sup>&</sup>lt;sup>4</sup> The cases providing for venue over jointly liable defendants do not help Plaintiff either because no concept of joint liability applies to this case.

home state in Illinois, rather than face transfer to St. Louis County. *Jackson v. Abbott Labs.*, *Inc.*, No. 3:15-cv-0186 (S. D. Ill. Feb. 25, 2015).

In describing the purpose of the venue statutes, Plaintiff utterly ignores the intention of the 2005 Act "to disallow venue-shopping, especially in suits against corporations." *Summary of the Committee Version of the Bill: Hearing on HCS HB 1304 Before the H. Comm. on Judiciary*, 92nd Gen. Assemb., 2nd Regular Sess. (Mo. 2004). The history of the 2005 Act, as described in Abbott's Opening Brief (pp. 50-56), points only one way; it was intended to drastically restrict forum shopping and curtail the number of lawsuits filed in St. Louis City. Plaintiff cannot and does not contest this purpose. The legislature accomplished this objective by limiting venue for disputes involving out-of-state injuries to the location of the corporation's registered agent. In Plaintiff's words, having cases tried in the location of the corporation's registered agent was precisely the "legislatively-chosen, defendant-centric shield against inconvenience" the legislature chose. (Br. 37).

Plaintiff suggests Abbott should have addressed the inconvenience and illogic of a St. Louis City forum over this Minnesota case through a personal jurisdiction challenge. (Br. 28, 44). Plaintiff's argument ignores the fact that this case was filed long before the Supreme Court changed the law of personal jurisdiction in *Daimler AG v. Bauman*, 134 S.Ct. 746 (2014). *See State ex rel. Norfolk Southern Railway Co. v. Dolan*, SC95514, 2017 WL 770977, at \*3 (Mo.banc Feb. 28, 2017) (describing prior Missouri cases as "no longer the law" after *Daimler*). Plaintiff also suggests that the litigation crisis in St. Louis City will be solved by application of this Court's decision in *State ex rel. Norfolk Southern Railway Co. v. Dolan*, SC95514, Slip. Op. (Mo. Feb. 28, 2017). (Br. 44). But *Norfolk* was a single plaintiff case. The issue here is whether Rule 52.05 can be used to extend the venue and jurisdiction of civil actions in multiple plaintiff cases in contravention of Rule 51.01. Even though the rationale of *Norfolk* should apply, this problem persists even after *Norfolk*. Indeed, rather than giving *Norfolk* the respect it is due, the St. Louis City Circuit Court recently refused to apply it in *Adler v. Boerhinger Ingelheim Pharms. Inc.*, No. 1522-CC11103-01 (Mo. Cir. Mar. 20, 2017). In that case with multiple plaintiffs, the Circuit Court found jurisdiction for all out-of-state plaintiffs because personal jurisdiction existed for the claim of a single St. Louis plaintiff. The issue of Rule 51.01's application to multi-plaintiff cases is not going away and should be resolved now by this Court.<sup>5</sup>

### **E.** Abbott Is Not Required To Demonstrate Prejudice.

Section 508.010 either permits out-of-state plaintiffs to use joinder to adjudicate out-of-forum injuries against out-of-state defendants, or it does not. No additional showing of prejudice is required for Abbott to prevail on its venue and joinder claims because these questions are purely legal. In Missouri, "[v]enue is determined solely by statute." *State ex rel. Ford Motor Co. v. Manners*, 161 S.W.3d 373, 375 (Mo. 2005). Questions of law, including statutory construction, are reviewed *de novo*, without

<sup>&</sup>lt;sup>5</sup> Since filing Abbott's Opening Brief, we count sixteen more cases filed joining over 1,070 out-of state plaintiffs.

considering whether the lower court's adjudication prejudiced the appealing party. *See, e.g., Hervey v. Missouri Dep't of Corr.*, 379 S.W.3d 156, 163–64 (Mo.banc 2012). Plaintiff cannot point to any case in which this Court interpreted a venue statute, found the trial court to be in error, and then required a showing of prejudice. And this Court did the opposite in *Igoe v. Dept. of Labor*, 152 S.W.3d 284 (Mo.banc 2005).

In practice, this Court carefully delineates between claims requiring prejudice and those that do not. In *Hervey*, for example, the Court reviewed a jury instruction question for prejudice and separately reviewed a question of statutory construction without considering prejudice. *Compare* 379 S.W.3d at 159 (reviewing jury instructions *de novo* and considering prejudice), with *id.* at 163 (construing statute *de novo* without considering prejudice). Plaintiff's argument to the contrary consists of an *ipse dixit* reliance on Rule 84.13, but that isn't "just how it is." Plaintiff offers no explanation how this Court does not routinely violate Rule 84.13 by adjudicating constitutional or statutory claims raising pure questions of law without considering prejudice. Strictly adhering to the text of the venue statute ensures that courts do not infringe the considered policy judgment of the legislature.

The venue statute and transfer provision employ mandatory language, underscoring that no additional prejudice showing is required on appeal. *See* R.S. Mo. § 508.010.4-.5 (venue "shall" be in certain counties); Mo. R. Civ. P. 51.045 (trial court "*shall* order a transfer of venue to a court where venue is proper"). Venue statutes protect defendants from forum-shopping litigants seeking to hale them into a venue unconnected to the subject of the suit to gain a strategic advantage. *See Leroy v. Great*  *W. United Corp.*, 443 U.S. 173, 183–84 (1979)(venue "protect[s] the defendant against the risk that a plaintiff will select an unfair or inconvenient place of trial"); *State ex rel De Paul Health Center v. Mummert* 870 S.W.2d 820, 821 (Mo.banc 1994)(Robertson, J., describing the "protracted procedural plotting to embrace or avoid the generous juries of the City of St. Louis"). No level of harm is acceptable in cases of improper venue.

A defendant forced to litigate a suit in an improper forum necessarily suffers prejudice—enough so that a party may challenge venue by extraordinary writ (as Abbott did here). *See State ex rel. Kansas City S. Ry. Co. v. Nixon*, 282 S.W.3d 363, 365 (Mo.banc. 2009) (writ to correct venue "necessary to prevent unnecessary, inconvenient and expensive litigation").<sup>6</sup> A defendant who wades through a full blown trial in an improper venue suffers even greater prejudice than one that obtains a writ. A trial court's misapplication of the statute necessarily harms a defendant by requiring it to answer a charge in a place where the legislature has determined it need not do so. This Court

<sup>6</sup> Contrary to Plaintiff's assertion (Br. 46), federal courts do not require a showing of prejudice for post-trial claims of improper venue. *See, e.g., Gulf Ins. Co. v. Glasbrenner*, 417 F.3d 353, 355 (2d Cir. 2005) (*de novo* review). Moreover, the Fifth Circuit case on which Plaintiff relies undercuts its argument: There, the court held that interlocutory review of venue determinations by writ prevents irreparable harm because waiting for direct appeal would mean that "the prejudice suffered cannot be put back in the bottle." *In re Volkswagen of America, Inc.*, 545 F.3d 304, 319 (5th Cir. 2008) (en banc).

should reject Plaintiff's prejudice argument; otherwise, erroneous venue rulings would be rendered effectively unreviewable on appeal.

# II.Plaintiffs' Claims Do Not Arise Out of the Same Transaction Or Series of<br/>Transactions Where They Are Separated By Eighteen Years and Do Not<br/>Involve the Same Warning.

Plaintiff's contention is that *any* plaintiffs, from *any*where, with *any* injury, spanning *any* time period involving *any* warning label, can join their claims together so long as they were allegedly injured by the same drug. This would result in virtually limitless joinder. Plaintiff's contention ignores the two requirements of Rule 52.05 that all of the claims must not only involve common questions of law or fact, but also arise from the "same transaction or occurrence or same series of transactions or occurrences."

## A. This Court's Review of the Propriety of Joinder is *De Novo*.

Plaintiff agrees that the interpretation of Rule 52.05(a) is a question of law reviewed *de novo*. (Br. 51). But in the next breath, Plaintiff claims that the denial of Abbott's motion to sever—which was solely based on the legal interpretation of joinder under Rule 52.05—should be reviewed for an abuse of discretion. (*Id.*). The Court should not be fooled.

Because the "permissive joinder of parties is fixed by Civil Rule," the trial court has **no discretion** to allow joinder where the rule does not so permit. *See State ex rel. Gulf Oil Corp. v. Weinstein*, 379 S.W.2d 172, 175 (Mo. App. 1964) (emphasis added). *See also Guess v. Escobar*, 26 S.W.3d 235, 239 n. 3 (Mo. App 2000) (recognizing that "where joinder is improper," a trial court "**must** sever upon motion, having **no discretion**  to do otherwise") (emphasis added).<sup>7</sup> Plaintiff cites *Levey v. Roosevelt Fed. Sav. & Loan Ass 'n*, 504 S.W.2d 241, 245 (Mo. App. 1973), for the proposition that determination of whether to permit the joinder of parties is reviewed for abuse of discretion. *Levey*, however, runs counter to every other Missouri appellate decision and is merely a stray statement the trial court did not abuse its discretion without any analysis of the proper standard of review or citation to authority.

## B. Joinder is Not Proper in These Failure-to-Warn Cases Where the Claims Are Based on Different Warning Labels, Different Locations, and Different Time Periods.

There is no question that plaintiffs joined here are unrelated to one another, that their mothers were prescribed Depakote at different times over an *eighteen*-year span by

<sup>&</sup>lt;sup>7</sup> The Court of Appeals misread *Guess* as holding that a motion to sever pursuant to Rule 52.05(a) is reviewed for abuse of discretion. (Slip Op. 8). In fact, *Guess* did not concern a motion to sever pursuant to Rule 52.05(a), but rather a motion to hold separate trials pursuant to Rule 66.02. *Guess* made a clear distinction between the two, noting that severance of claims for separate *trials* pursuant to Rule 66.02 is left to the trial court's discretion, while the trial court has *no* discretion to do anything but sever where joinder is improper under Rule 52.05(a). *See Guess*, 26 S.W.3d at 239 & n. 3. Plaintiff's citation to *Wilson v. Bob Wood & Assoc., Inc.*, 633 S.W.2d 738 (Mo. App. 1981), suffers from the same problem. The motion under review in that case was one under Rules 66.01 and 66.02. *Id.* at 743.

different physicians based on *different* warning labels, and that their claims involve the application of *different* (and often times, conflicting) states' laws. Plaintiffs urge the Court to turn a blind eye to these significant differences and instead focus only on the fact that the joined plaintiffs' mothers took Depakote. That lone fact cannot justify joinder

Plaintiffs' claims do not involve the same transaction/occurrence or series of transactions/occurrences—an independent and separate requirement that must be met for joinder. *See* Rule 52.05(a). These are warnings cases. Plaintiffs' claims concern alleged inadequacies in a Depakote warning label; yet, their claims do not even concern the same label. And, each warning label must be judged in terms of the different scientific knowledge available at that time. The prescribing of Depakote in different states to different patients for different conditions by different doctors over a period of 18 years involving different medical knowledge and different warning labels is not the same transaction/occurrence or series of transactions/occurrences

Plaintiff argues that "[t]he serial sale of the same product" by Abbott is "under *Dally*, a related series of transactions/occurrences." (Br. 56). Actually, the *Dally* court's reasoning demonstrates that joinder is not proper here. *Dally* is one in a long line of successive car accident cases where a subsequent accident caused aggravation of the plaintiff's injuries from the first accident, and its holding was limited to that scenario. Specifically, the *Dally* Court held that in aggravated injury cases involving a single plaintiff, joinder is permitted because the option to hold a joint trial is *necessary* to apportion liability between the two defendants for the injury. *See Dally*, 248 S.W.3d at 618 ("Were permissive joinder to be prohibited in cases of aggravated, successive

injuries, separate trials would afford each defendant the opportunity to impute the bulk of liability to the other tortfeasor(s)").<sup>8</sup> That is not the case here, where joint trials are not only unnecessary, but unworkable.

Plaintiff does not dispute that courts throughout the country, including in Missouri, hold that plaintiffs in pharmaceutical product liability cases are not properly joined merely by virtue of having taken the same medication. See, e.g., Cumba v. Merck & Co., Inc., No. 08-cv-2328, 2009 WL 1351462, at \*1 (D. N.J. May 12, 2009) ("The majority of courts to address joinder in the context of drug liability cases have found that basing joinder merely on the fact that the plaintiffs ingested the same drug and sustained injuries as a result thereof is insufficient to satisfy Rule 20(a)'s [same transaction/occurrence] requirement."). Instead, she urges this Court to ignore those cases as not precedential. While it is true that this Court has never faced the propriety of joinder in a pharmaceutical case involving different plaintiffs, different warnings labels, different states, different physicians, and different time periods, the precedent from across the country points clearly in a single direction. Plaintiff's inability to find any pharmaceutical cases to support her position is evident, as the cases Plaintiff cites are federal remand decisions where the court did not rule on a motion to sever, but rather addressed the limited issue of whether joinder was *fraudulent*—a different analysis that

<sup>&</sup>lt;sup>8</sup> Plaintiff's citation to *Prempro* (Br. 56, n. 31) is also unavailing: "[W]e make no judgment on whether plaintiffs' claims are *properly* joined under Rule 20." *In re Prempro Prods. Liab. Litig.*, 591 F.3d 613, 623 (8th Cir. 2010) (emphasis original).

requires the defendant to show "egregious" and "grossly improper" joinder. *See, e.g. Gracey v. Janssen Pharms.*, No. 4:15-cv-407 (CEJ), 2015 WL 2066242, at \*2 (E.D. Mo. May 4, 2015).<sup>9</sup>

# C. The Need for Individual Trials Demonstrates the Impropriety of Joinder Here.

Plaintiff asserts, without citation, that the purpose of the joinder rule is to create as much efficiency as possible while preserving the rights of the parties (Br. 53). Plaintiff then claims that efficiencies are gained and prejudice minimized by joining her claims at the outset, but separating them for trial and appeal. But, as described above, Missouri courts interpreting Rule 52.05(a) make clear that the rationale underlying permissive joinder is to minimize prejudice by permitting joint trials and appeals where individual trials would be prejudicial—not the opposite. *See Dally* 248 S.W.3d at 618. *See also* 

<sup>&</sup>lt;sup>9</sup> Plaintiff cites to the Southern District of Illinois consolidated proceedings in *In re Depakote*, 12-cv-52, for her assertion that "courts have held that joinder is proper in pharmaceutical cases, and that it is proper to try joined cases one at a time." (Br. 60). Those cases—filed in Abbott's home state—were removed to federal court under the Class Action Fairness Act, a unique federal statute specifically designed for multiplaintiff lawsuits. The court there never ruled on the propriety of joinder under Rule 20(a). Abbott also notes that Judge Shaw, in remanding this case from federal court, did not analyze whether Plaintiffs met the same transaction/occurrence requirement. (L.F. 2191-95).

*Kinsey*, 394 S.W.3d at 449 (Rule 52.05(a) "is liberally construed to allow for a more expedient resolution of the case, as a single jury is able to more effectively apportion damages between two defendants than two juries sitting separately..."). The rules do not contemplate, and Missouri law does not endorse initial joinder of unrelated plaintiffs against a single defendant with later separate trials and separate appeals, for the sole purpose of gaming the venue statute.

# III. Plaintiff's Theory of Inadequacy of the Warning Is Based on an Allegedly Assumed Duty that Has No Evidentiary Support.

This is not a case where a warning was not given or where a warning was inadequate such that the risks could not be appreciated. To the contrary, Abbott warned of the risk of the precise injury suffered by Plaintiff. Ms. Vititoe's prescribing physician—the learned intermediary—saw the warning and was aware of the risk. Ms. Vititoe's doctors repeatedly warned her at least four different times of the risk of birth defects, including spina bifida, if she should become pregnant while taking Depakote. Ms. Vititoe heard and appreciated those warnings, and even herself expressed concerns about the applicable risks and a desire to avoid Depakote while pregnant if possible. No Minnesota court has held a warning inadequate under similar circumstances. If ever there was a case to hold a warning adequate as a matter of law, this is it.

## A. Plaintiff Does Not Contest that the 2002 Depakote Warning Met the Three Required Elements for Adequacy Under Minnesota Law.

Plaintiff agrees (Br. 66) with Abbott that a warning is legally adequate under Minnesota law where it "(1) attract[s] the attention of those [to whom it is directed]; (2) explain[s] the mechanism and mode of injury; and (3) provide[s] instructions on ways to safely use the product to avoid injury." *Gray v. Badger Mining Corp.*, 676 N.W.2d 268, 274 (Minn. 2004). Curiously, though, after reciting these elements of a legally adequate warning, Plaintiff never addresses them again. Plaintiff's silence speaks volumes—she does not contest the adequacy of the Depakote warning under established Minnesota law.

*First*, Plaintiff does not contest that Depakote's Black Box warning of the risk of birth defects—including specifically neural tube defects (e.g., spina bifida)—attracted the attention of prescribing physicians. Indeed, the evidence is undisputed, as her own labeling expert testified that the Black Box warning "is meant to catch the eye" and "the interest of the reader" (Tr. 1035), and Dr. Jacoby read the label and knew that Depakote could cause spina bifida and other birth defects. (Tr. 1273-74).

Second, Plaintiff does not contest that the warning label explained the specific mechanism and mode of her injury—neural tube defects. See 2002 Depakote Label (A 16; L.F. 3195 ) ("VALPROATE CAN PRODUCE TERATOGENIC EFFECTS SUCH AS NEURAL TUBE DEFECTS (E.G. SPINA BIFIDA)"). Again, she cannot credibly do so, as Dr. Jacoby testified that, prior to Plaintiff's conception, he "explained to [Ms. Vititoe] about neural tube defects and how they worked and what we're worried about and why they can be serious." (Tr. 1240-41).

*Third*, and finally, Plaintiff does not contest that the warning provided instructions on how to avoid injury—namely, by avoiding the use of Depakote during pregnancy or avoiding becoming pregnant while on Depakote. The undisputed evidence demonstrates that this warning was not only made, but was appreciated by Ms. Vititoe and her prescribing physicians. Due to Depakote's stated risks of birth defects, Ms. Vititoe discontinued Depakote and switched to another medicine when she was contemplating pregnancy. (L.F. 3236-38). When the other medicine failed to control Ms. Vititoe's seizures, she expressed a desire to go back on Depakote and was again warned to avoid pregnancy while on it. (L.F. 3268).

Because Plaintiff does not contest that Abbott's 2002 warning met all elements of a legally adequate warning under Minnesota law, Plaintiff did not have a legally submissible case as a matter of law. That the adequacy of a warning is normally a question of fact is thus entirely beside the point. Minnesota law—just like Missouri law—recognizes that undisputed material facts do not require a jury trial, and the adequacy of a warning is no different. *See, e.g., Spencer v. Matula*, No. C2-90-1409, 1990 WL 195414, at \*1 (Minn. App. Dec. 11, 1990) (affirming summary judgment holding that warning was adequate as a matter of law).

## **B.** Comity Requires This Court to Decline Plaintiff's Invitation to Expand Minnesota Law to Impose a Duty Never Contemplated by Minnesota.

Unable to dispute that the 2002 Depakote warning met the requirements for legal adequacy under Minnesota law as set forth in *Badger*, Plaintiff asks this Court to approve a drastic expansion of Minnesota law to impose on drug manufacturers a duty to provide a *comparative* warning—i.e., a warning that compares the risk of its drug to other drugs. Such a duty has never been required by the Minnesota courts or legislature and would encourage Minnesota plaintiffs to sue in Missouri to escape their own state's law.

Plaintiff's theory is that the 2002 Depakote label was inadequate because it did not say that Depakote should be used "only as a last resort"—*i.e.*, only after all other, "safer" medicines are tried (Br. 67). Whether Abbott had a duty to provide that kind of comparative warning—particularly where the warning otherwise satisfied the requirements of Minnesota law described above—is purely a question of law. *See Glorvigen v. Cirrus Design Corp.*, 796 N.W.2d 541, 552 (Minn. App. 2011)

("[R]espondents' contention that the duty to warn by providing adequate instructions for safe use includes an obligation to train the end user to proficiency is unprecedented. And in the absence of precedent we are not willing to extend the duty to warn to encompass this obligation").

Plaintiff offers no Minnesota authority for the expanded duty she proposes. In fact, Plaintiff implicitly admits no such independent duty to provide comparative warnings exists under Minnesota law, instead claiming this Court should impose an expanded duty here because "Abbott's warnings voluntarily undertook a comparison with other drugs" by including the following sentences in its label:

THERE ARE MULTIPLE REPORTS IN THE CLINICAL LITERATURE WHICH INDICATE THAT THE USE OF ANTIEPILEPTIC DRUGS DURING PREGNANCY RESULTS IN AN INCREASED INCIDENCE OF BIRTH DEFECTS IN THE OFFSPRING. ALTHOUGH DATA ARE MORE EXTENSIVE WITH RESPECT TO TRIMETHADIONE, PARAMETHADIONE, PHENYTOIN, AND PHENOBARBITAL,

## REPORTS INDICATE A POSSIBLE SIMILAR ASSOCIATION WITH THE USE OF OTHER ANTIEPILEPTIC DRUGS.

(Br. 71; A 19, L.F. 3198). Plaintiff claims these two sentences in the 2002 Depakote label imposed a duty on Abbott never before imposed under Minnesota law, and rendered the spina bifida warning and other significant birth defect warnings inadequate. Plaintiff thus stakes her entire theory of liability on the argument that "[o]nce Abbott undertook the comparison ('similar association'), its warning was required to state the comparison accurately." (*Id.*). That theory, however, is based solely on an attorney distortion of this statement that no witness and no evidence supports.

Plaintiff's claim that the "similar association" language constitutes an inaccurate statement of comparative risk is nothing more than attorney argument and lacks any citation to the record. Plaintiff's warning expert, Dr. Blume, was never asked and provided no testimony about this statement. In contrast, Dr. James Willmore<sup>10</sup> testified that this statement was *accurate* and describes the type of risk, not a comparison of the relative degree of risk:

- Q: -- "reports indicate a possible similar situation (sic) with the use of other antiepileptic drugs." Was that a true statement as of 2001-2002?
- A: Yes, a similar association, yes.

<sup>&</sup>lt;sup>10</sup> Dr. Willmore is a leading neurologist who has been practicing medicine for nearly fifty years.

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- Q: How do you interpret that statement?
- A: This is a statement that says that all of these drugs have risk of birth defects.
- Q: There is nothing in there giving a ranking?
- A: There's no rank order in there, no, sir.

(Tr. 1459). Not only is the record devoid of evidence that this statement is "inaccurate" or was intended to compare the degree of risk among AEDs, but this statement also cannot be tied to Dr. Jacoby's prescribing decision, as he testified that this particular statement in the label "is not telling me much of anything." (Tr. 1219). As a result, not only is there no evidence to support Plaintiff's argument distorting the meaning of this statement, but the argument is rebutted by the testimony of the prescribing doctor.

Plaintiff also vaguely asserts that "Abbott misstated the risk of its drug." (Br. 74). But the 2002 Depakote Label accurately stated the risk of spina bifida by including the incidence rate calculated by the Centers for Disease Control. Any argument to the contrary is simply without evidentiary support, as Plaintiff's own expert, Dr. Oakley, testified that his professional estimate of the risk of spina bifida after *in utero* exposure to Depakote is 1-2 percent—the precise statistic in the Depakote Label. (Tr. 598-99). Plaintiff cannot credibly claim that any other spina bifida incidence rate was scientifically established or should have been included.

In the face of a warning of the precise injury at issue, Plaintiff combs the label for any other alleged "inaccuracy" on which to stake her claim. Plaintiff now contends that statement regarding *other* birth defects is inaccurate: "sufficient data to determine the incidence of these congenital anomalies is not available." (Br. 18, 74). But again, Plaintiff has no evidentiary support for this bald assertion. Although Dr. Blume was asked point-blank on direct examination whether this was "a correct statement," she did not testify that the statement was inaccurate. (1028-1029). Noticeably absent is any evidence that sufficient data existed to determine the incidence of the other congenital anomalies. Dr. Willmore testified that sufficient data was not available in 2002 and that this statement accurately reflected the state of the medical science at that time:

- Q: --"involving various body systems compatible and incompatible with life have been reported. Sufficient data to determine the incidence of these congenital anomalies is not available." Was that a true medical statement as of—based on the medical science as of 2001-2002?
- A: Yes.

(Tr. 1461). And Dr. Jacoby likewise testified that he interpreted the statement to mean that "not only do we have spina bifida to worry about, but there is also congenital abnormalities, but there is not enough data to make any comments basically." (Tr. 1220).

Attorney argument is no substitute for evidence. Having grounded her entire case on the legal theory that Abbott voluntarily assumed a duty to give comparative warnings because of the "similar association" language, Plaintiff's claim falls apart. Plaintiff cannot ask this Court to impose a new duty to give comparative warnings based on the argument that Abbott assumed that duty by including comparative information that was inaccurate, when no witness testified that the statement was in fact a comparison or was in fact inaccurate. In reality, no evidence contradicts Dr. Willmore's testimony that the "similar association" statement does not constitute a comparison and is completely accurate. Plaintiff likewise lacks evidentiary support for her claim that any other statements in the label are "inaccurate." The entire foundation for Plaintiff's failure to warn claim is built on a fallacy and it should be rejected.

## IV. <u>Minnesota Law Does Not Permit the Imposition of Punitive Damages On The</u> <u>Evidence Presented In This Case</u>.

## A. Plaintiff's Claim for Punitive Damages Is Even More Egregious than Her Failure to Warn Theory.

Plaintiff does not dispute that her punitive damages theory must be based on the same theory as her claim for compensatory damages, but it also must satisfy the higher standard of clear and convincing evidence of a conscious disregard for safety. As a result, the imposition of punitive damages presents an even stronger case for reversal. Plaintiff acknowledges that her claim of compensatory damages is based on "the danger of Depakote as compared to other AEDs," and that this comparative risk is "what made a difference to Dr. Jacoby." (Br. 89-90). Thus, the alleged duty to provide comparative risk information is the duty on which Plaintiff's entire case rests. But as described above, Plaintiff has no factual predicate for her assertion that Abbott assumed a duty to provide comparative warnings. Plaintiff claims that Abbott assumed this duty by including what she describes as an "inaccurate" statement regarding a "similar association," but the only expert testimony about this statement in the label is that it was not comparative and was

accurate. Abbott cannot be held liable for punitive damages for including a statement in the FDA-approved label that no expert said was inaccurate. The punitive damages evidence is not just "somewhat thin," as Judge Ohmer said—it is non-existent.

Plaintiff's fixation on internal marketing documents, and statutory factors that relate to the amount of punitive damages rather than submissibility, ignores that proximate cause is a required element for punitive damages just as it is for compensatory damages. *See, e.g., Wikert v. N. Sand & Gravel, Inc.*, 402 N.W.2d 178, 182 (Minn. App. 1987) (noting punitive damages "are awarded only where the harm complained of is the result of conduct done" with "disregard for the rights of others"). Plaintiff presented no evidence that Dr. Jacoby was exposed to such marketing, let alone that such marketing is what prompted him to prescribe Depakote to Ms. Vititoe. Thus, it cannot form the basis for an award of punitive damages.

#### **B.** *In re Levaquin* is Controlling.

*In re Levaquin* involved the same scenario here, except that the warning given was much less prominent than Depakote's Black Box warning, and in fact was located in the last paragraph of the "Warnings" section of the label "surrounded by more than fifteen pages of other small print." 700 F.3d 1161, 1167 (8th Cir. 2012). Nevertheless, Plaintiff claims the cases are "in stark contrast" because, unlike the defendant in *Levaquin*, "Abbott delivered a warning that omitted information and was false and misleading." (Br. 87). As described above, there is no evidence to support that argument. And, in any case, it is the exact argument the Plaintiffs in *Levaquin* advanced. *See* 700 F.3d at 1169 (noting that the district court improperly upheld the punitive damages award based on

evidence that the defendant "knew of the potential for the higher tendon toxicity of Levaquin, assisted in the design of the Ingenix study, allegedly to hide that potential..., and then failed to adequately warn prescribers.").

There is no dispute that Abbott warned of the precise risk of the precise injury suffered by Plaintiff, and did so in the most prominent warning available. There is no dispute that Abbott also warned of the risk of other birth defects. And there is no dispute that Dr. Jacoby knew, appreciated, and acted on those warnings. That the Depakote Label did not use the exact words Plaintiff would like, or did not include every study that Plaintiff thinks it should have, is not sufficient grounds for the imposition of punitive damages. This is a point made soundly by the Eighth Circuit in *In re Levaquin. See id.* ("On this record, this motive allegation is mere speculation").

In applying another state's laws, this Court should defer to the arbiters of that state's laws, particularly where, as here, the Eighth Circuit has so clearly addressed this exact factual scenario under Minnesota law. Otherwise, plaintiffs will continue to abuse venue and joinder in Missouri to attempt to escape the application of their own state's laws.

## C. No Case Has Affirmed the Imposition of Punitive Damages Under These Circumstances.

Plaintiff cannot point to any appellate authority from anywhere to support the imposition of punitive damages where a drug's label warned of the precise risk of the precise injury experienced by the plaintiff. She certainly cannot point to any Minnesota authority, as *In re Levaquin* quite clearly held the opposite. It is no surprise, then, that

Plaintiff seeks to shift focus away from Minnesota and appellate authority by citing trial court decisions from outside of Minnesota finding that a claim for punitive damages could survive summary judgment. (Br.75-76). But a trial court's finding that a claim for punitive damages survives summary adjudication under a different state's punitive damages law (such as Illinois, which does not require clear and convincing evidence) simply does not equate to a finding of deliberate disregard under Minnesota's clear and convincing standard. To be clear, no court, anywhere, has ever upheld the imposition of punitive damages against Abbott for inadequate warnings in the Depakote Label. In fact, aside from this case, no jury anywhere has ever found that Abbott failed to adequately warn of the risks of birth defects, much less that it did so with deliberate disregard for the safety of others.

## D. Due Process Requires Reversal.

Plaintiff does not dispute that Minnesota law has never imposed a duty to provide comparative warnings. Nonetheless, Plaintiff claims not only that this duty can be extrapolated from Minnesota law, but also that it can provide a basis for punitive damages. This exact argument was made, and flatly rejected, in *In re Levaquin*. *See In re Levaquin*, 700 F.3d at 1169 (reversing punitive damages award despite evidence that the defendant "knew of the potential for the higher tendon toxicity of [its drug]," tried to "hide that potential," and then "failed to adequately warn prescribers."). An authoritative decision on the precise standard under Minnesota law is dispositive; decisions from other courts on summary judgment dealing with different standards under different state laws

are not. It is precisely for this reason Abbott did not have fair notice of this alleged requirement and punitive damages cannot survive Due Process analysis.

Plaintiff is also wrong in her assertion that Abbott waived its due process argument. Abbott preserved this argument in its post-trial briefing. *See* L.F. 2311 (Citing *State Farm* and arguing that "since no Minnesota appellate court has ever imposed a duty on a product manufacturer to provide comparative warnings, Abbott had no conceivable expectation that its purported failure to test, compare, and issue warnings concerning the comparative teratogenicity, including those of its competitors, would subject it to such severe punishment.").

## V. <u>CONCLUSION</u>

Because Plaintiff was first injured outside of Missouri, venue and joinder in the City of St. Louis were improper, and the judgment should be vacated. Alternatively, the Court should remand the case with instructions to enter judgment in favor of Abbott on Plaintiff's failure-to-warn claim and should vacate the punitive damages award as inconsistent with Minnesota law.

Respectfully submitted,

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## **CERTIFICATE OF COMPLIANCE**

The undersigned herby certifies, pursuant to Missouri Supreme Court Rule 84.06(c), that this brief complies with Rule 55.03 and the length limitations contained in Rule 84.06(b) in that there are 7,750 words in the brief (except the cover, signature block, certificate of service, and certificate of compliance) according to the word count of the Microsoft Word word-processing system used to prepare the brief.

/s/ Dan H. Ball

## **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on April 25, 2017, the foregoing was filed electronically with the Clerk of the Court to be served by operation of the court's electronic filing system on all counsel of record.

/s/ Dan H. Ball