IN THE
SUPREME COURT OF MISSOURI

No. SC96151

MIASIA BARRON, *et al.*,

Plaintiffs/Respondents,

v.

ABBOTT LABORATORIES INC.,

Defendant/Appellant.

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

SUBSTITUTE BRIEF OF DEFENDANT/APPELLANT

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JURISDICTIONAL STATEMENT

This is a personal injury case in which a St. Louis City jury rendered a verdict for Plaintiff-Respondent Maddison Schmidt of $15 million in compensatory damages and $23 million in punitive damages. The Circuit Court entered final judgment for Plaintiff under Rule 74.01(b) in accordance with the verdict on June 30, 2015. (A 11, L.F. 2139-2141, 2146-2155, 3534). Defendant-Appellant Abbott Laboratories Inc. ("Abbott") timely filed motions for judgment notwithstanding the verdict or, in the alternative, for new trial, (L.F. 2233, 3537), and the Circuit Court denied those motions on September 16, 2015. (A 13, L.F. 3539). Abbott timely filed its notice of appeal to the Eastern District Court of Appeals on September 24, 2015. (L.F. 3528). After the Court of Appeals issued its opinion affirming the judgment on November 8, 2016, Abbott timely filed a motion for rehearing or in the alternative for transfer to the Supreme Court. The Court of Appeals transferred this case pursuant to Rule 83.02 by Order of January 5, 2017.

Jurisdiction of this appeal lies in this Court under Article V, § 10 of the Missouri Constitution based on the Order of January 5, 2017, transferring the case to this Court.

INTRODUCTION

Plaintiff Maddison Schmidt is a Minnesota resident born with birth defects in Minnesota after her mother took anti-seizure medication in Minnesota prescribed by a Minnesota doctor and sold by Abbott, a company headquartered in Illinois. Despite the absence of any Missouri connection, Plaintiff joined with nineteen other out-of-state plaintiffs and four Missouri plaintiffs, including two from St. Louis, to file a single case in St. Louis City Circuit Court. After defeating Abbott's motions to sever and transfer, Plaintiff's case proceeded to trial alone.

This case is one of many: a deluge of mass tort cases overwhelming the docket of the St. Louis City Circuit Court. Plaintiffs' attorneys from across the country are bringing their plaintiffs to St. Louis City because, to date and contrary to law, the Circuit Court has not told them no. There are over 145 such mass tort cases currently pending in St. Louis City with over 9,700 plaintiffs. These cases have on average sixty-two out-of-state plaintiffs and one plaintiff who resides in the City of St. Louis.[1] The trials of these cases to date have lasted an average of seventeen trial days and have involved exclusively out-of-state plaintiffs.[2] Cases like this one fill the Circuit Court's docket, negatively

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[1] We obtained this data from Case.net records.

[2] The trials of which we are aware are: *Foster, et al. v. Pfizer Inc., et al.*, No. 1222-CC02441-01 (Mo. Cir. 2015) (California plaintiff tried in 8-day jury trial); *Walker, et al. v. Monsanto Co., et al.*, No. 1122-CC09621-01 (Mo. Cir. 2016) (Alaska, Michigan, and Oklahoma plaintiffs tried in 18-day jury trial); *Hogans, et al. v. Johnson & Johnson, et*

impacting the timely access of St. Louisans to the justice system. In fact, if even a quarter of the plaintiffs in these presently pending cases go to trial, it would take the judges assigned to the eighteen trial divisions of the Circuit Court more than *seven continuous years of trial* to wade through just these 145 cases—and more cases are being filed every month.

The expected volume of trials will require St. Louisans to disproportionately fulfill their civic duty as jurors to sit in judgment on disputes that have no discernible connection to St. Louis. Those seven continuous years of trials would require over 278,000 St. Louis City residents to be summoned for jury duty (based on the 115 jurors summoned for this trial). That number exceeds the roughly 235,000 St. Louis City residents who are age 21 or over, which itself likely exceeds the number of residents actually eligible for jury service. Because jurors are only eligible to serve every two years, these mass-tort cases alone will exhaust the supply of eligible St. Louis jurors. § 494.430.1(1) & .7, RSMo (2013).

These trials will also cost millions of dollars in taxpayer money in judicial resources. Jury pay alone will cost over $14 million. And that is a drop in the bucket next to the budget required to keep eighteen trial divisions continuously operating for

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al., No. 1422-CC09012-01 (Mo. Cir. 2016) (Alabama, California, and South Dakota plaintiffs tried in separate 3-week jury trials); *Swann, et al. v. Johnson & Johnson, et al.*, No. 1422-CC09326-01 (Mo. Cir. 2017) (Tennessee plaintiff; trial ongoing as of date of this filing).

seven straight years to resolve the disputes of out-of-state plaintiffs, much less the negative economic impact of taking tens of thousands of St. Louisans out of the workforce to serve as jurors. In the meantime, the Circuit Court must still handle the criminal, family, juvenile, and civil matters necessary for the normal functioning of the justice system and the local community.

In these mass-tort cases, justice for out-of-state disputes is taking a front seat, while Missouri parties wait. In the future, Missouri parties in all types of cases may be waiting, while judges and jurors sort out these out-of-state disputes. Because choice of law principles require the Circuit Court (and Missouri appellate courts) to apply the law of states with which they have little experience or expertise, mistakes will likely be made. Without enforcement of the venue provisions of the Tort Reform Act of 2005, out-of-state plaintiffs will continue to avoid the courts and even the law of their home states, and these problems will get further out of control. St. Louis City Circuit Court has become a forum-shopping magnet for mass tort plaintiffs across the country—all to the detriment of the perception of justice.

These problems do not exist in the abstract. In this case, Plaintiff's mother was taking Depakote, an Abbott prescription drug approved by the FDA to treat epilepsy, when she became pregnant with Plaintiff. At that time, Abbott's Depakote Label had a "Black Box" Warning—the strongest FDA-permitted warning—informing physicians that Depakote could cause spina bifida if taken during pregnancy. Before Plaintiff was conceived, both Plaintiff's mother and the prescribing physician were aware that

Depakote increases the risk of spina bifida *and* that Depakote had an increased risk compared to other anti-seizure medications.

Plaintiff's Minnesota case was the first selected for trial. And despite Abbott's warning about the risk of the precise injury at issue, the Circuit Court's application of a novel extension of Minnesota warning law resulted in a $15 million compensatory award, and an erroneous application of Minnesota punitive damages law resulted in a $23 million punitive award—more than $19 million greater than any punitive damages award ever upheld on appeal under Minnesota's punitive damages statute. The Circuit Court's expansive misinterpretation of Minnesota law has now made it the forum of choice for Minnesota residents (and likely those of other states) to escape proper application of their own state's law.

The judgment should be reversed to correct these manifest errors of law for the following reasons:

1. The City of St. Louis was not a proper venue. Under the Missouri venue statute, the only potentially proper Missouri venue for tort claims in which the plaintiff was first injured outside of Missouri is the county in which the defendant corporation's registered agent is located (St. Louis County). § 508.010.5, RSMo (2013). The Circuit Court interpreted the venue statute as meaning that Plaintiff (along with 19 other non-Missouri plaintiffs) could create venue for their claims in the City of St. Louis simply by joining those claims with the claims of unrelated plaintiffs from the City of St. Louis. But this Court and Rule 51.01 have erected a clear prohibition against the use of joinder

to extend the venue of the Missouri courts. The Circuit Court's interpretation of the venue statute ignores the plain language of Rule 51.01 and is wrong as a matter of law.

2. This Court should still reverse even if joinder could create venue, because the joinder of these plaintiffs' claims was improper here. These claims do not arise out of the same transaction, occurrence or series of transactions or occurrences, and the factual and legal differences among the claims would have made it impossible to try the cases together. Each of these cases involves a different prescribing decision by a different physician in response to a different patient with a different medical history with a different Depakote warning label based on a different level of scientific knowledge at a different point in time and a different alleged injury governed by the law of a different state. Indeed, the Circuit Court ultimately realized that it could not try the cases together and instead decided to conduct *individual* trials and permit individual appeals. As a result, the joinder of these claims serves little purpose other than to squeeze them all into the City of St. Louis. Reversal here will undoubtedly result in the filing of these types of cases where they belong—in states that have some connection with the disputes.

3. The use of venue and joinder to create what amounts to a national forum for the resolution of mass-tort cases suffers for the additional reason that the Circuit Court could not possibly be an expert in the applicable law of the fifty states. In this case, the Circuit Court erroneously accepted Plaintiff's argument that Minnesota law required Abbott to warn physicians not only about Depakote's risk of spina bifida, but also that Depakote's overall risk for all birth defects was comparatively higher than that of other antiepileptic drugs. But Plaintiff can point to no Minnesota state decisions holding that a

manufacturer has a duty to warn about how its own product's risks compare to those of other manufacturers. And Missouri courts should not expand another state's laws. Expansion of Minnesota law should occur in Minnesota courts, lest Missouri courts become the forum of choice for Minnesota plaintiffs seeking a declaration of "alternative" Minnesota law from Missouri courts.

4. The Circuit Court also erred in applying Minnesota's punitive damage statute. Abbott's conduct does not meet the controlling Minnesota statutory standard for punitive damages—clear and convincing evidence of "deliberate disregard for the rights and safety of others." Minn. Stat. Ann. § 549.20. Abbott's use of a Black Box spina bifida warning—the strongest type of warning permitted by the FDA—is not a deliberate disregard for the rights and safety of others. Indeed, under Minnesota law, a prescription drug warning even *less prominent than a Black Box Warning* precludes a punitive damages award. In fact, this case represents the first appellate court in the country to uphold an award punitive damages based on a failure to warn of the risk of a possible injury when the risk of that injury was specifically described in an FDA-mandated Black Box Warning. And although Plaintiff criticizes Abbott's conduct regarding Depakote, none of that conduct was a proximate cause of her injuries and therefore cannot support a punitive damages award under Minnesota law.

STATEMENT OF FACTS

The essence of Plaintiff's case was her contention that Depakote has a higher risk of birth defects than other anti-epileptic drugs ("AEDs") and that Abbott should have warned that Depakote has a higher comparative risk than other AEDs and should only be used if all other treatment options had failed. As described below, Plaintiff's experts testified that Depakote had a greater number of adverse events relative to other AEDs and that Depakote caused Plaintiff's injuries, while the prescribing physician of Plaintiff's mother testified he would not have prescribed Depakote to Plaintiff's mother had he known of this greater risk.

Although we set forth the facts in the light most favorable to the verdict, *see Hayes v. Price*, 313 S.W.3d 645, 648 (Mo. banc 2010), we note that the facts critical to the resolution of this appeal are largely not contested and we provide a detailed summary below for additional context.

I. THE RISKS ASSOCIATED WITH DEPAKOTE, EPILEPSY, AND PREGNANCY.

Epilepsy is a medical condition that causes seizures, which can lead to serious injury and death. (Tr. 1173-75, 1242). Epilepsy presents even greater challenges for women who want to become pregnant because seizures during pregnancy can also cause serious injury and death to the fetus. (Tr. 1244-45). Adding to these challenges is the fact that the use of AEDs during pregnancy carries an additional risk of birth defects. (Tr. 1042).

Prescription drug manufacturers warn physicians about a drug's potential risks through an FDA-approved package insert—commonly referred to as the drug's "label." Many prescription drug labels, including the Depakote Label, also are published annually in the *Physicians' Desk Reference* ("PDR"). (Tr. 1059-60). FDA regulations specify the format for prescription drug labels, and this format includes a number of sections that inform physicians about a drug's potential risks. For example, where the drug presents a risk "that may lead to death or serious injury," the FDA may require the label to include a Black Box Warning about that risk. *See* 21 C.F.R. § 201.57(e) (2002). No stronger type of warning exists. (Tr. 1082-83). Manufacturers may not change the content of a Black Box Warning without FDA review and approval. (Tr. 1079)

A. Abbott Began Warning the Healthcare Community About the Birth Defect Risks Associated with Depakote in 1983.

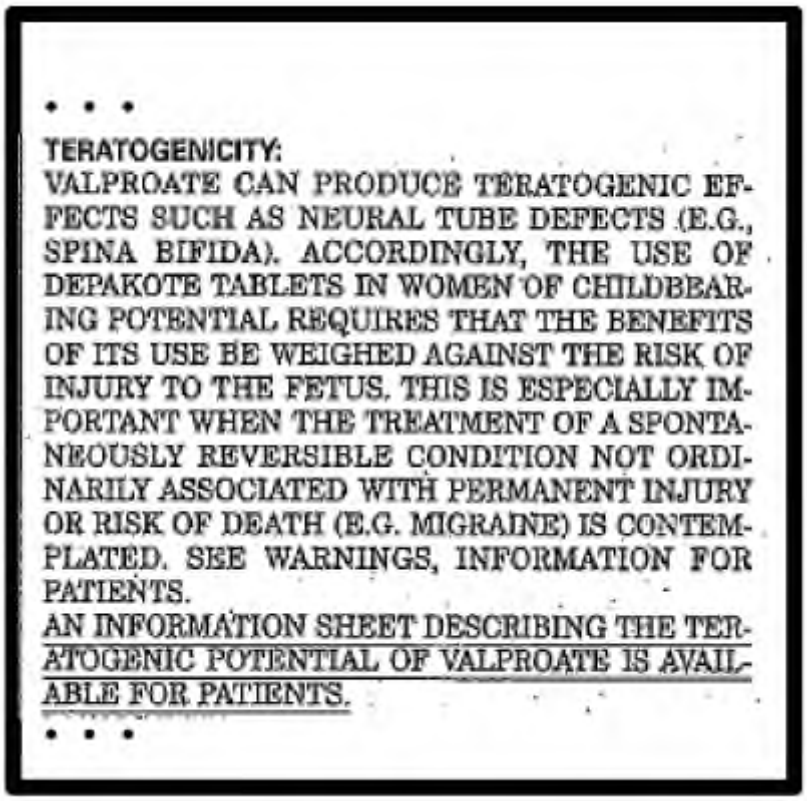
An editorial note in the October 29, 1982, edition of the CDC's *Morbidity and Mortality Weekly Report* set forth its estimate of the spina bifida risk posed by Depakote: "Given the United States' spina bifida rate of approximately six per 10,000 births and a relative risk of 20.6 (as indicated by the French data), the estimated risk of valproic acid-exposed women having children with spina bifida is approximately 1.2%."[3] (L.F. 3145). Soon thereafter, Abbott disseminated thousands of FDA-approved "Dear Doctor" letters advising doctors of this new data and the "increased risk of specific congenital defects." (L.F. 3019, 3147; Tr. 556:24 to 557:3). Abbott also sought and obtained permission from

[3] Depakote is also known as "valproate" or "valproic acid."

the FDA to revise the Depakote Label to include a four-paragraph Usage in Pregnancy section that disclosed the CDC's 1.2% spina bifida risk estimate. (L.F. 821, 3019).

B. Abbott Included a Black Box Warning of Teratogenic Risks, Including Spina Bifida, on the Depakote Label by 1996.

The 1996 addition of a Black Box Warning concerning birth defect risks provided the most "serious type of warning mandated" by the FDA and the Black Box is the first thing doctors read in the Depakote Label. (Tr. 1079-80; *see id.* at 1077 (they "[c]atch attention"), 1078-79 (are controlled by FDA), 1080-81 (most significant way to stress a warning or safety information about a drug), 1083, 1088). That Black Box Warning specifically warned that Depakote can cause spina bifida:



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TERATOGENICITY:
VALPROATE CAN PRODUCE TERATOGENIC EFFECTS SUCH AS NEURAL TUBE DEFECTS (E.G., SPINA BIFIDA). ACCORDINGLY, THE USE OF DEPAKOTE TABLETS IN WOMEN OF CHILDBEARING POTENTIAL REQUIRES THAT THE BENEFITS OF ITS USE BE WEIGHED AGAINST THE RISK OF INJURY TO THE FETUS. THIS IS ESPECIALLY IMPORTANT WHEN THE TREATMENT OF A SPONTANEOUSLY REVERSIBLE CONDITION NOT ORDINARILY ASSOCIATED WITH PERMANENT INJURY OR RISK OF DEATH (E.G. MIGRAINE) IS CONTEMPLATED. SEE WARNINGS, INFORMATION FOR PATIENTS.
AN INFORMATION SHEET DESCRIBING THE TERATOGENIC POTENTIAL OF VALPROATE IS AVAILABLE FOR PATIENTS.

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Plaintiff's warnings expert, Cheryl Blume, Ph.D., acknowledged that a Black Box Warning "is the most serious type of warning mandated by the U.S. Food and Drug Administration," is "considered the strongest labeling form," and "is the most significant way to stress a warning or safety information about a drug." (Tr. 1082-83). She also acknowledged the FDA directed Abbott to add this Black Box Warning to the Depakote Label in 1996, (Tr. 1039, 1103-04), and that in 2002 Depakote was the only anti-epileptic drug with a Black Box Warning about spina bifida and birth defects. (Tr. 1042, 1104).

According to Dr. Blume, Black Box Warnings "catch the eye, the interest of the reader" and warn "about serious adverse reactions or specialty problems." (Tr. 1034-35, 1080). Dr. Robert G. Jacoby, the prescribing physician for Plaintiff's mother, also interprets Black Box Warnings as providing "special warnings." (Tr. 1211, 1272-74). The only other neurologist to testify during trial, Dr. L. James Willmore, added that a Black Box Warning "says stop. It's a serious warning. And you've got to think it through." (Tr. 1457).

C. Abbott's FDA-Approved Depakote Label in 2002 Included a Black Box Warning, a Usage in Pregnancy Section, and a Pregnancy Category D Rating That Conveyed the Spina Bifida Risks.

The Black Box Warning also appeared at the beginning of the 2002 Label and accompanied Depakote in the 2002 edition of the *PDR*. (L.F. 3195; Tr. 1035, 1102-03, 1211-12, 1235-36, 1272-74, 1456-57). Depakote was the only AED in 2002 with a Black Box Warning concerning birth defects. (Tr. 1039-40, 1103, 1448-49, 1456-5).

Additional sections of FDA-mandated labels provide information about a drug's risks, including a section titled "Warnings." 21 C.F.R. § 201.57(e) (2002). The "Warnings" section of the 2002 Depakote Label included ten paragraphs about risks of birth defects. For example, the "Warnings" section stated: "THE CENTERS FOR DISEASE CONTROL (CDC) HAS ESTIMATED THE RISK OF VALPROIC ACID EXPOSED WOMEN HAVING CHILDREN WITH SPINA BIFIDA TO BE APPROXIMATELY 1 TO 2%." (A 19, L.F. 3198). One of Plaintiff's expert witnesses on birth defects, Dr. Lammer, confirmed that this warning of a 1-2% risk is entirely accurate. (Tr. 820 ("Q. Well, what you told us in the report very precisely was that there was a one – between one and two percent absolute risk, correct? A. For spina bifida? Q. Yes, sir. A. Yes.")).

The "Warnings" section of the 2002 Depakote Label also stated that, in addition to spina bifida, "OTHER CONGENITAL ANOMALIES (EG, CRANIOFACIAL DEFECTS, CARDIOVASCULAR MALFORMATIONS AND ANOMALIES INVOLVING VARIOUS BODY SYSTEMS), COMPATIBLE AND INCOMPATIBLE WITH LIFE, HAVE BEEN REPORTED." (A 19, L.F. 3198). The Usage in Pregnancy subsection of the Label specifically warned:

> The prescribing physician will wish to weigh the benefits of therapy against the risks in treating or counseling women of childbearing potential. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

(L.F. 3198). No other AED included labeling with such a precise estimate about a specific birth defect. (Tr. 1239-40, 1449).

When Plaintiff was conceived in 2002, prescription drug labels also included a "Pregnancy category." 21 C.F.R. § 201.57(f)(6) (2002). The FDA promulgated five pregnancy risk categories, from Category A (studies have failed to demonstrate risk to the fetus) to Category X (evidence has demonstrated risk to the fetus that clearly outweighs any benefit to the mother). (A 23, L.F. 3207). The 2002 Depakote Label notified physicians that the FDA had assigned Depakote to the second-most severe category—Category D, (A 20, L.F. 3199), which means:

> **POSITIVE EVIDENCE OF RISK.** Studies in humans, or investigational or post-marketing data, have demonstrated fetal risk. Nevertheless, potential benefits from the use of the drug may outweigh the potential risk. For example, the drug may be acceptable if needed in a life threatening situation or serious disease for which safer drugs cannot be used or are ineffective.

(A 23, L.F. 3207). Some other AEDs were rated in 2002 as "Category C" drugs. (L.F. 3212). That designation means that:

> **RISK CANNOT BE RULED OUT**. Adequate, well-controlled human studies are lacking, and animal studies have shown a risk to the fetus or are lacking as well. There is a chance of fetal harm if the drug is administered during pregnancy; but the potential benefits may outweigh the potential risk.

(L.F. 3207). AEDs classified as Category C drugs were recognized as "safer" than Category D drugs. (Tr. 1084-85).

It is undisputed that in 2002, when Plaintiff was conceived, Depakote was the *only* AED available that carried both a Black Box Warning for birth defects and a Pregnancy Category "D" rating. These additional and stronger warnings in the Depakote Label as compared to other AED labels provided prescribing physicians a warning of Depakote's relative risk as compared to other AEDs. Notwithstanding the disclosed birth defect risks, neurologists continued to determine that Depakote was the medically appropriate choice to treat the epilepsies of some women of childbearing years in 2002. For example, the American Academy of Neurology's recommendation in effect at that time was: "The choice of antiepileptic drugs for women with epilepsy during the reproductive years should be that deemed most appropriate for seizure type." (Tr. 1258-59).

II. THE MEDICAL HISTORY AND PREGNANCY OF PLAINTIFF'S MOTHER.

Tiffany Vititoe, a long-time resident of Minnesota, first reported problems with epilepsy when she was a middle-school-aged child in the 1990s. (Tr. 1187). She initially took Klonopin (clonazepam) (L.F. 3236), but when Klonopin no longer worked, her physician switched her to Depakote. (Tr. 1427, 1540-41, 1562). Ms. Vititoe did well on Depakote. (L.F. 3238, Tr. 1189, 1200, 1223, 1269-70, 1437, 1439, 1466).

A. In 2000, A Suspected Pregnancy Prompted Ms. Vititoe to Switch from Depakote to Another AED That Her Doctors Considered Safer During Pregnancy.

In 2000, Ms. Vititoe's doctors switched her from Depakote to Lamictal because of a possible pregnancy and the belief that Lamictal "might be a preferable medication to Depakote upon which to become pregnant." (L.F. 3240, 3236). During an October 2, 2000, visit with a neurologist, Ms. Vititoe reported that she "had not had her menstrual period for a two month period of time and there were concerns of her being pregnant. She had a negative pregnancy test. The plan was to try to switch her over to Lamictal from Depakote due to the potential teratogenic potential of Depakote relative to Lamictal." (L.F. 3236, 3238). Even before Ms. Vititoe's pregnancy test came back negative, her neurologist had concluded that Ms. Vititoe would "need a broad-spectrum agent. Lamictal, category C, is presumably safer in pregnancy. . . . [Ms. Vititoe] is convinced that Depakote not only has malformation risks but caused her to have two miscarriages in the past and wants to go off the medicines." (L.F. 3238).

In 2000 and 2001, Ms. Vititoe's doctors memorialized her appreciation of the spina bifida risks of Depakote, that she stopped taking Depakote because of these increased risks, and that she switched to Lamictal to lower her risk of having a child with birth defects:

- Ms. Vititoe discussed with her neurologist that Lamictal "has a lesser risk in terms of teratogenic side effects when compared with Depakote" during a December 21, 2000, visit. (L.F. 3236).

- During a second ER visit on June 29, 2001, Ms. Vititoe reported that she was taking "Lamictal and Folate because she is trying to get pregnant." (L.F. 3245).
- During a July 7, 2001, ER visit, Ms. Vititoe was offered Depakote to prevent breakthrough seizures, but she "did not really want to be loaded again with [Depakote]. It had been discontinued previously. It was switched to Lamictal previously with the thought she might sometime in her 20s be trying to get pregnant and should not be taking [Depakote] at that time." (L.F. 3249).
- On August 8, 2001, Ms. Vititoe returned to the ER, reporting that she had discontinued her previous Depakote use because "she was trying to get pregnant." (L.F. 3252).
- During a September 9, 2001, ER visit, Ms. Vititoe experienced a seizure so severe that hospital personnel had to provide her with oxygen and employ a waist restraint. Ms. Vititoe then expressed a desire to go back on Depakote. (L.F. 3255).
- An October 4, 2001, ER note includes the following observation: "Apparently, [Ms. Vititoe] had no trouble with Depakote, but apparently if she got pregnant, did not want to be on the Depakote." (L.F. 3259).

B. Ms. Vititoe Resumed Taking Depakote While Acknowledging the Risk.

After October 4, 2001, Ms. Vititoe resumed taking Depakote while under Dr. Jacoby's care. (L.F. 3242). Dr. Jacoby had read the Depakote warning label, and he interpreted the label as stating that Depakote can cause spina bifida and other birth defects. (Tr. 1273-74 ("Q. So there was no question in your mind, Doctor, that Depakote

could cause not only birth defects—not only spina bifida but other birth defects as well, right? A. Correct.")). He also acknowledged that another physician had previously switched Ms. Vititoe from Depakote to Lamictal because of the teratogenic potential of Depakote relative to Lamictal. (Tr. 1280).

Dr. Jacoby thereafter reminded Ms. Vititoe repeatedly about the birth defect risks of Depakote:

- October 5, 2001: "She understands there is a risk with this medi[c]ation with regards to pregnancy, and she has taken folic acid 1 mg twice a day." (L.F. 3262).
- October 31, 2001: "She understands the Depakote can cause fetal defects in children. . . . She told me she did not want to change the medication no matter what level it was, even if it was a little too high, simply because she is feeling really good at this time." (L.F. 3265).
- January 29, 2002: "She understands that Depakote is a medication that she needs to be on long term. She also understands that she should not get pregnant on this medication because of the risk of neural tube defects." (L.F. 3268).

C. Ms. Vititoe Conceived While Taking Depakote, and Plaintiff Was Born with Spina Bifida.

Plaintiff was conceived in August 2002. Her spina bifida developed within the first 28 days. (Tr. 354, 487, 1441). Although Ms. Vititoe had not seen Dr. Jacoby since January 29, 2002, she missed her September 5, 2002 appointment. (Tr. 1304-05; L.F. 3275). Ms. Vititoe subsequently advised Dr. Jacoby's office that she "was wondering about getting [pregnant] and being on seizure medication;" although she did "not want to

become [pregnant] at [that] time," she indicated that "in the future she is thinking about it." (L.F. 3275).

On approximately September 30, 2002, Ms. Vititoe advised Dr. Jacoby's office about her pregnancy. (L.F. 3283). Dr. Jacoby wanted to make "an appointment to see her a few days later. [Ms. Vititoe] unfortunately could not come to that appointment because of some difficulty with her ride." (L.F. 3272). During Ms. Vititoe's next office visit (October 31, 2002), Dr. Jacoby memorialized how he had advised her about the birth defect risks of Depakote: "Clearly in my notes, I explained to her [on October 31, 2001] so that she understood Depakote could cause fetal defects in children and she should take Folic acid 1 mg a day." (L.F. 3272).

After a February 3, 2003, ultrasound revealed that Plaintiff had spina bifida, Dr. Jacoby recorded that he had made sure that Ms. Vititoe "was aware of the difficulties with baby issues, in particular with regard to neural tube defects and spina bifida." (L.F. 3289). On April 24, 2003, Plaintiff was born and had surgery for her spina bifida the next day. (L.F. 3278). By that point, the neurological damage from Plaintiff's spina bifida already had occurred. (Tr. 407-10). The spina bifida resulted in paralysis below the waist and brain injuries that, according to one of her expert witnesses, renders her intellectual functioning "in the mildly mentally retarded range." (Tr. 775-76).

III. PROCEEDINGS BELOW

Although the Depakote Label contained a Black Box Warning about spina bifida, Plaintiff alleged that Abbott also had a duty to warn under Minnesota law that Depakote's overall risk for all birth defects was higher than that of all other AEDs on the market and

therefore Depakote should be used in women of childbearing potential only if all other AEDs have failed to control the woman's seizures. Although Ms. Vititoe knew Depakote was riskier than the medication she had been on, Plaintiff also alleged that Abbott's conduct with regard to Depakote warranted punitive damages under Minnesota's punitive damages statute.

Rather than file her lawsuit in a Minnesota court, Plaintiff filed her lawsuit in the Circuit Court of the City of St. Louis, along with nineteen other plaintiffs born outside of Missouri and four plaintiffs born in Missouri. (L.F. 35, 142).[4] Abbott moved to sever the claims as misjoined under Rule 52.05; and Abbott moved to transfer the non-Missouri plaintiffs' claims, including Plaintiff's claims, to the Circuit Court for St. Louis County because Abbott's registered agent is located in that County and therefore that County is the only potentially proper venue in Missouri for those claims. (L.F. 64). *See* § 508.010.5, RSMo (2013) (stating that where "the plaintiff was first injured outside the

[4] The non-Missouri plaintiffs hail from 12 states: Florida, Georgia, Illinois, Louisiana, Minnesota, Montana, New York, North Carolina, Oklahoma, Pennsylvania, Tennessee and Texas. The Missouri plaintiffs hailed from Grundy County, Webster County, and St. Louis City. When referring to the "plaintiffs" in the petition, Abbott is referring to individuals who alleged that they suffered birth defects as a result of *in utero* exposure to Depakote. The petition also included as plaintiffs parents and guardians of the individuals alleging birth defects from Depakote.

state of Missouri," the proper venue is "any county where a defendant corporation's registered agent is located").

But the Circuit Court denied Abbott's venue motion because the petition included twin sisters who alleged they were born with birth defects in the City of St. Louis. (A 1-10, L.F. 475, 481-82). In doing so, the Circuit Court did not discuss section 508.010.5 of the venue statute and determined that because the City of St. Louis was a proper venue for the twin sisters, the non-Missouri plaintiffs could create venue in the City of St. Louis for their claims by joining them with the claims of the twin sisters. (*Id.*). The Circuit Court stated that the joinder of the twenty-four plaintiffs' claims was proper because each plaintiff alleged he or she was "damaged" by Depakote. (A 7, L.F. 481). The Circuit Court added that "any issues of [juror] confusion or improper consideration of evidence" inherent in a trial involving twenty-four plaintiffs from thirteen different states could "be resolved at trial by effective use of jury instructions." (A 6, L.F. 480).

Abbott subsequently sought severance and transfer of the non-City of St. Louis plaintiffs' claims via petitions for writs of mandamus and writs of prohibition in the Court of Appeals and this Court, but both courts denied the petitions without opinion. Less than three months after this Court denied Abbott's writ petition, the Circuit Court decided that it would not conduct a joint trial of all plaintiffs' claims after all. Instead, the Circuit Court ordered each side to nominate two plaintiffs for separate *individual* trials. (L.F. 486-87). Plaintiffs' counsel nominated Plaintiff Maddison Schmidt for the first individual trial, and her trial took place in May 2015.

At trial, Plaintiff presented her warnings expert, Dr. Cheryl Blume, Ph.D., to explain why the 2002 Depakote Label was inadequate.[5] Dr. Blume opined that the label was inadequate because it should have warned that Depakote's overall risk of birth defects was greater than that of all other AEDs on the market and therefore Depakote should be used in women of child-bearing potential only when all other AEDs have failed to control the woman's seizures. (Tr. 1023-24). Dr. Blume agreed, however, that Depakote was the only AED on the market in 2002 that carried a Black Box Warning for birth defects, which she acknowledged is the strongest warning type and is the most significant way to stress a warning about a drug. (Tr. 1082-83, 1042, 1104). She also acknowledged that drugs labeled with a rating of A to C would be considered "safer" than Depakote. (Tr. 1087-88 ("Q. Ma'am, C rating means it's a safer drug? A. Well, C rating means that they do not have demonstrated fetal anomalies as they do with a D. Q. Did you just say, Dr. Blume, that a C rating means it's a safer drug? Did you just say that? A. I did.")).

Dr. Blume also testified that the Depakote Label in 2002 "did not adequately reflect the landscape, if you will, in the literature of the studies that had addressed birth

[5] Dr. Blume is not a medical doctor, but a pharmacologist and former pharmaceutical company employee; she now owns and operates a consulting company that provides expert witness services to plaintiffs in pharmaceutical product liability cases and advises pharmaceutical companies on, among other things, labeling issues. (Tr. 954-56, 967).

defects associated with Depakote" and that, in her opinion, the scientific and medical literature changed between 1984 and 2002, but Abbott's label was not sufficiently updated to reflect those changes. (Tr. 1020, 1024-25). She further testified that "consistently within these studies the weight of evidence would suggest that across these studies the most—the greatest number of events were observed in those women and their babies who had received Depakote relative to other antiepileptics." (*Id.*). Plaintiff also presented evidence regarding Abbott's marketing of Depakote, including testimony that Abbott's strategy was to position Depakote as a first-line treatment agent. (*See, e.g.*, L.F. 2358-59; 2375-76).

Dr. Jacoby, the prescribing physicians, also testified. Dr. Jacoby had read the Depakote Warning by 2002 and knew its content. (Tr. 1216). Dr. Jacoby knew about the spina bifida incidence rate by 2002. (Tr. 1217). He also knew that Depakote was rated as a Category D drug. (Tr. 1213-16, 1454-55). Had the Depakote Label warned that it should only be used if all other treatment options had failed, Dr. Jacoby testified that he would have followed that warning. (Tr. 1315-16). Similarly, had the Depakote Label warned that Depakote was the most teratogenic AED, Dr. Jacoby testified that he would not have prescribed it for Plaintiff's mother. (Tr. 1316). Finally, Plaintiff presented the testimony of Dr. Edward Lammer, a pediatrician and geneticist, who evaluated Plaintiff to determine the cause of her birth defects (Tr. 752-53). Dr. Lammer testified that "it's highly likely" that Maddison's birth defects were caused by exposure to Depakote. (Tr. 792).

At the close of Plaintiff's case, and again at the close of Abbott's case, Abbott moved for a directed verdict on Plaintiff's claim and on her demand for punitive damages. (L.F. 2043, 2129). Abbott argued, among other things, that the 2002 Depakote Label was adequate as a matter of Minnesota law because it included a Black Box and other warnings about spina bifida—the precise injury at issue—and that Abbott had no duty under Minnesota law to warn how Depakote's overall risk of birth defects compared to that of all other AEDs on the market. (*Id.*). The Circuit Court denied Abbott's motions from the bench. (A 25-26, Tr. at 1576-77). In doing so, the Circuit Court did not address whether Minnesota law places a duty on manufacturers to warn about how their product's risks compare to those of other manufacturers' products. (*Id.*) The Circuit Court also observed that Plaintiff's case for punitive damages was "somewhat thin." (A 26, Tr. 1577).

The jury subsequently found in Plaintiff's favor and awarded her $15 million in compensatory damages and $23 million in punitive damages. (L.F. 3534). The jury's vote on punitive damages was 9-3. (Tr. 1783). The punitive damages award was $19 million greater than any award ever upheld on appeal under Minnesota's punitive damages statute. In its post-trial motion for judgment notwithstanding the verdict or, in the alternative, new trial, Abbott renewed its venue and directed verdict arguments and argued that cumulative evidentiary errors warranted a new trial. (*See* L.F. 2233, 2260). The Circuit Court denied Abbott's motion in a two-page order. (A 13-14, L.F. 3539). Plaintiff then moved to have a separate judgment entered on her claim under Rule

74.01(b). (L.F. 2139-2141). The Circuit Court granted the motion and entered final judgment on June 30, 2015. (A 11).

On September 24, 2015, Abbott timely filed its Notice of Appeal from the Circuit Court's judgment. (L.F. 3528). The Eastern District Court of Appeals affirmed the Circuit Court's judgment in an Opinion dated November 8, 2016. Abbott subsequently moved the Court of Appeals for rehearing or transfer to this Court pursuant to Rules 84.17 and 83.02, arguing that the Court of Appeals overlooked and misapplied important aspects of both Missouri and Minnesota law. The Court of Appeals invited Plaintiffs to file a response to Abbott's motion, which they did. On January 5, 2017, the Court of Appeals granted Abbott's application for transfer to this Court and denied Abbott's motion for rehearing as moot.

POINTS RELIED ON

1. **THE CIRCUIT COURT ERRED IN DENYING ABBOTT'S MOTION TO TRANSFER PLAINTIFF'S CLAIMS BECAUSE VENUE IN ST. LOUIS CITY WAS IMPROPER UNDER THE VENUE STATUTE IN THAT PLAINTIFF WAS FIRST INJURED OUTSIDE OF MISSOURI AND ABBOTT'S REGISTERED AGENT IS LOCATED IN ST. LOUIS COUNTY.**

   Section 508.010, RSMo (2013)

   Rule 51.01, Missouri Rules of Civil Procedure

   State ex rel. Kinsey v. Wilkins, 394 S.W.3d 446 (Mo. App. 2013)

   State ex rel. Turnbough v. Gaertner, 589 S.W.2d 290 (Mo. banc 1979)

2. **THE CIRCUIT COURT ERRED IN DENYING ABBOTT'S MOTION TO SEVER THE PLAINTIFFS' CLAIMS, BECAUSE (A) THE 24 PLAINTIFFS' CLAIMS DID NOT ARISE OUT OF THE SAME TRANSACTION, OCCURRENCE OR SERIES OF TRANSACTIONS OR OCCURRENCES IN THAT THE PLAINTIFFS' MOTHERS WERE PRESCRIBED DEPAKOTE AT DIFFERENT TIMES BY DIFFERENT PHYSICIANS UNDER DIFFERENT CIRCUMSTANCES AND PLAINTIFFS ALLEGED DIFFERENT INJURIES, AND (B) BECAUSE IT WAS IMPOSSIBLE TO CONDUCT A FAIR TRIAL OF ALL PLAINTIFFS' CLAIMS IN THAT THERE WERE SIGNIFICANT FACTUAL AND LEGAL DIFFERENCES BETWEEN THOSE CLAIMS.**

Rule 52.05, Missouri Rule of Civil Procedure

Guess v. Escobar, 26 S.W.3d 235 (Mo. App. 2000)

State ex rel. Gulf Oil Corp. v. Weinstein, 379 S.W.2d 172 (Mo. App. 1964)

3. **THE CIRCUIT COURT ERRED IN DENYING ABBOTT'S MOTIONS FOR DIRECTED VERDICT AND JUDGMENT NOTWITHSTANDING THE VERDICT ON PLAINTIFF'S FAILURE TO WARN CLAIM BECAUSE THE DEPAKOTE LABEL WAS ADEQUATE AS A MATTER OF MINNESOTA LAW IN THAT THE LABEL (A) ATTRACTED THE ATTENTION OF THOSE TO WHOM IT WAS DIRECTED, (B) EXPLAINED THE MECHANISM AND MODE OF INJURY, AND (C) EXPLAINED HOW TO SAFELY USE THE PRODUCT TO AVOID INJURY.**

Gray v. Badger Mining Corp., 676 N.W.2d 268 (Minn. 2004)

Ashley Cnty. Ark. v. Pfizer, Inc., 552 F.3d 659, 673 (8th Cir. 2009)

4. **THE CIRCUIT COURT ERRED IN DENYING ABBOTT'S MOTIONS FOR DIRECTED VERDICT AND JUDGMENT NOTWITHSTANDING THE VERDICT ON PLAINTIFF'S DEMAND FOR PUNITIVE DAMAGES BECAUSE PLAINTIFF DID NOT PRESENT CLEAR AND CONVINCING EVIDENCE THAT ABBOTT DELIBERATELY DISREGARDED THE RIGHTS AND SAFETY OF OTHERS IN THAT ABBOTT WARNED PRESCRIBING PHYSICIANS OF DEPAKOTE'S RISK OF SPINA BIFIDA VIA A BLACK BOX WARNING AND ABBOTT DID NOT HAVE FAIR**

NOTICE UNDER THE DUE PROCESS CLAUSE THAT COMPARATIVE WARNINGS WERE REQUIRED UNDER MINNESOTA LAW.

Minn. Stat. Ann. § 549.20

In re Levaquin Prods. Liab. Litig., 700 F.3d 1161 (8th Cir. 2012)

U.S. Constitution, Amend. V, XIV

Minn. Constitution Art. I, § 7

ARGUMENT

1. THE CIRCUIT COURT ERRED IN DENYING ABBOTT'S MOTION TO TRANSFER PLAINTIFF'S CLAIMS BECAUSE VENUE IN ST. LOUIS CITY WAS IMPROPER UNDER THE VENUE STATUTE IN THAT PLAINTIFF WAS FIRST INJURED OUTSIDE OF MISSOURI AND ABBOTT'S REGISTERED AGENT IS LOCATED IN ST. LOUIS COUNTY.

The Court should vacate the judgment because the Circuit Court erred in denying Abbott's motion to transfer venue. "In Missouri, venue is determined solely by statute." *State ex rel. Kinsey v. Wilkins*, 394 S.W.3d 446, 449 (Mo. App. 2013). Therefore, this Court applies the *de novo* standard of review to the Circuit Court's interpretation of the venue statute. *See Lumetta v. Sheriff of St. Charles County*, 413 S.W.3d 718, 720 (Mo. App. 2013) ("The interpretation of a statute is a pure question of law, and therefore we give the circuit court's interpretation no deference."); *McCoy v. The Hershewe Law Firm, P.C.*, 366 S.W.3d 586, 592 (Mo. App. 2012) (stating that where a trial court's "venue decision is governed by the interpretation of a statute, the ruling is a question of law").

A. Section 508.010.5 Controls Venue for Plaintiff's Claim.

Missouri's venue statute provides two different rules for tort cases—one rule for cases "in which the plaintiff was first injured in the state of Missouri," § 508.010.4, RSMo (2013); and the other rule for cases "in which the plaintiff was first injured outside of the state of Missouri," § 508.010.5, RSMo (2013). Where "the plaintiff was first injured in the state of Missouri," the proper venue is "the county where the plaintiff was

first injured" by the defendant's allegedly negligent or wrongful conduct. § 508.010.4, RSMo (2013). But where, as here, "the plaintiff was first injured outside the state of Missouri," the proper venue is "any county where a defendant corporation's registered agent is located." § 508.010.5(1), RSMo (2013). Under the plain text of section 508.010.5, the only potentially proper Missouri venue for Plaintiff's claim was St. Louis County because she "was first injured outside the state of Missouri" and that is the county in which Abbott's registered agent is located. (L.F. 118).

While the court acknowledged Abbott's contention that § 508.010.5 was dispositive of venue, the court did not address that provision as a result of its joinder analysis. Abbott respectfully suggests that the language of § 508.010.5 is clear, unambiguous, and controlling. There is no dispute here that Plaintiff Schmidt was first injured in Minnesota and that Abbott's registered agent is located in St. Louis County. Had Plaintiff brought her claim alone, it is undisputed that section 508.010.5 applies and that venue is improper in St. Louis City. That should end the analysis. Indeed, to hold otherwise would be to interpret the statute in a way that ignores the most relevant provision of it.

Nevertheless, in denying Abbott's venue motion, that is exactly what the Circuit Court did. (*See* A 1, L.F. 475). This was error. *See, e.g.*, *State ex. rel. Womack v. Rolf*, 173 S.W.3d 634, 638 (Mo. banc 2005) ("Courts will reject an interpretation of a statute that requires ignoring the very words of the statute"); *Hadlock v. Dir. of Revenue*, 860 S.W.2d 335, 337 (Mo. banc 1993) (noting "we cannot ignore the final portion of" the

statute at issue). Because the Circuit Court's interpretation of the venue statute ignores section 508.010.5, this Court should reject that interpretation.

B. Permissive Joinder Cannot Be Used To Expand Venue.

Instead of applying section 508.010.5, the Circuit Court held that section 508.010.4—which deals with in-state injuries—applied because the out-of-state plaintiffs joined their claims with twin St. Louis plaintiffs under Rule of Civil Procedure 52.05. (A 7-8, L.F. 481-82). The central issue presented by this point is thus whether a plaintiff may use permissive joinder under Rule 52.05 to piggyback on the venue of another plaintiff with whom she is joined. The Circuit Court held that Plaintiff could, and the Court of Appeals determined that proper venue is "contingent upon whether there is proper joinder of the parties." (Slip Op. at 4). That is simply not so. The Rules of Civil Procedure cannot be used to extend the statutory venue of civil actions. That has been settled law under both the Missouri Rules of Civil Procedure and the cases of the Missouri Supreme Court for at least the last thirty-seven years.

Rule 51.01 is, in the words of this Court, both clear and explicit: "These Rules shall not be construed to extend or limit the jurisdiction of the courts of Missouri, or the venue of civil actions therein." As the Court of Appeals noted only four years ago, "simply joining two separate causes of action in a single petition does not create venue over both actions." *Kinsey*, 394 S.W.3d at 450. But, in this case, the Court of Appeals overlooked Rule 51.01 and instead cited to the statement in *State ex rel. Allen v. Barker*, 581 S.W.2d 818, 824 (Mo. banc 1979), that "issues of proper venue are contingent upon

whether there is proper joinder of parties."[6] This statement is flatly incorrect as inconsistent with Rule 51.01, and this Court has recognized this mistake in *Allen* time and time again. Indeed, this Court even has retracted expressly this statement from *Allen*.

The first case to "reject this contention" that "joinder is said to result in venue as to the counts so joined" was decided just eight months after *Allen*. *State ex rel. Turnbough v. Gaertner*, 589 S.W.2d 290, 292 (Mo. banc 1979). In *Turnbough*, plaintiff brought suit against two defendants in the City of St. Louis. Looking at each defendant separately, venue was proper in St. Louis as to one defendant, but not the other. Plaintiff contended that "venue as to all is created in any county wherein any one of the several defendants resides even though there would not have been venue as to one (or more) of the counts if filed separately in that county." *Id.* at 291-292. The Supreme Court "reject[ed] this contention, holding that venue could not "be established by means of Rule 52.05(a) when it would not have existed without such joinder." *Id.* at 292.

> [Plaintiff's] argument ignores the language of Rule 51.01 which clearly and explicitly states that the Rules of Civil Procedure, of which Rule 52.05(a) is a part, "shall not be construed to extend or limit the jurisdiction of the Courts of Missouri or the venue of civil actions therein." This limitation is underscored by the Committee Note to Rule 51.01, promulgated when the

[6] *Allen* involved a suit against several defendants for their involvement in the publication of a single allegedly defamatory statement and has no factual similarity to this case. 581 S.W.2d at 820-21.

> rule was first adopted. It observes that even though venue may be procedural rather than substantive within the meaning of Mo. Const. art. V, s 5, which grants rule making authority to the Supreme Court, and even though establishment of venue by procedural rule may be permissible, such a determination was avoided by the Court by the disclaimer contained in Rule 51 that venue *was not* to be established or limited on the basis of the Rules of Civil Procedure. Therefore, assuming, but not deciding, that joinder of Counts I and II was authorized by Rule 52.05(a), that fact would not establish venue as to Count II under the provisions of s 508.010(2). To hold otherwise would mean that, contrary to the express provisions of Rule 51.01, venue as to Count II would be established by means of Rule 52.05(a) when it would not have existed without such joinder.

Id. at 292 (emphasis in original).

This core holding that joinder cannot be used to expand venue for additional parties has been reaffirmed in one decision after another since that time. *State ex rel. Jinkerson v. Koehr*, 826 S.W.2d 346, 348 (Mo. banc 1992) (affirming *Turnbough* and holding, "Simply joining the two separate causes of action in a single petition does not create venue over both actions"); *State ex rel. Sims v. Sanders*, 886 S.W.2d 718, 720 (Mo. App. 1994) (following *Turnbough* and *Jinkerson*); *State ex rel. BJC Health System v. Neill*, 121 S.W.3d 528, 530 (Mo. banc 2003) (describing *Allen* as "incorrectly stating that 'the question of venue is contingent upon proper joinder'"); *State ex rel. Nixon v. Dally*, 248 S.W.3d 615, 617 (Mo. banc 2008) ("permissive joinder provision of Rule 52.05(a)

authorizes joinder of claims ... [i]n cases where venue is proper as to both defendants"); *State ex rel. Kinsey v. Wilkins*, 394 S.W.3d 446, 453 (Mo. App. 2013) ("Because Rule 51.01 forbids interpreting a civil rule to expand venue, joinder under Rule 52.05(a) could not serve as a vehicle to expand venue to Greene County").

Because Rule 51.01 does not permit Rule 52.05 to expand the venue of the Circuit Court, the judgment should be vacated.

C. The History of Missouri's Venue Statutes and the 2005 Tort Reform Act Confirm that Joinder Cannot Be Used To Game the Venue Analysis.

The history of the 2005 Tort Reform Act confirms the lack of venue here. "The purpose of the venue statutes is to provide a convenient, logical and orderly forum for litigation." *See, e.g.*, *State ex rel. McDonald's Corp. v. Midkiff*, 226 S.W.3d 119, 123 (Mo. banc 2007); *State ex rel. Lebanon Sch. Dist. R-III v. Winfrey*, 183 S.W.3d 232, 237 (Mo. banc 2006). "In this way, they do protect defendants from suit being filed against them in counties 'all over the state' to which neither they nor the cause of action have any connection." *Lebanon Sch. Dist*, 183 S.W.3d at 237.[7] *See, e.g.*, *Anglim v. Missouri Pac.*

[7] "[F]rom its inception, the concept of venue was intended to protect parties from litigation in locations where they face an unfair disadvantage." Peter L. Markowitz & Lindsay C. Nash, *Constitutional Venue*, 66 Fla. L. Rev. 1153 (2014). Venue statutes "discourage [plaintiffs] . . . from shopping for the most generous jury pool," which "encourage[s] nonresident corporations that intend to do business in the state to register

R. Co., 832 S.W.2d 298, 302 (Mo. banc 1992) (related doctrine of *forum non conveniens* "is designed to prevent a plaintiff from using a liberal venue statute to vex, oppress or harass a defendant by bringing a suit in a forum unrelated to the parties or cause of action."). The history of Missouri's venue statutes, and particularly the Tort Reform Act of 2005, demonstrates that section 508.010.5 was intended to prevent the type of forum shopping so obviously at work in these cases.

Throughout its early history, Missouri allowed venue for actions in counties where the defendant was an inhabitant or could be found. Digest of the Laws of the Missouri Territory § 16, p. 248 (1818) ("in the county in which [defendant] is an inhabitant" or, if the defendant can be found there, "the county in which the plaintiff resides at the time of serving such process"); RSMo ch.2, § 3, p. 622 (1825) (in the county in which the defendant "is an inhabitant" or in the country "in which the plaintiff resides" if the defendant can be "found in the county in which the plaintiff resides at the time of serving such process").

The first Missouri statute to specify venue for suits against corporations also focused on the presence of the defendant, rather than the defendant's registered agent. RSMo ch. 34, art. II., § 4, p. 238 (1845) ("[s]uits against corporations shall be commenced in the proper court of the county wherein the general meetings of the members, or the officers of such corporation, have usually been holden, or by law, ought

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with the Secretary of State." Alan J. Lazarus, *Jurisdiction, Venue, and Service of Process Issues in Litigation Involving A Foreign Party*, 31 Tort & Ins. L.J. 29, 67 (1995).

to have been holden"); *see also State ex rel. Webb v. Satz*, 561 S.W.2d 113, 114 (Mo. banc 1978) ("The predecessor of § 508.040 goes back to the Revised Statutes of 1845."). In 1855, the venue provision in Article II §4 was revised to state that "[s]uits against corporations shall be commenced, either in the county where the cause of action accrued, or in any county where such corporation shall have, or usually keep, an office or agent for the transaction of their usual and customary business." RSMo ch. 34, art. II, § 4, p. 377 (1855). Apart from minor revisions, this version of the statute "provided the basis" for the corporate venue statute for more than 100 years. *See* Edward D. Robertson III, *Missouri Venue and House Bill 1304: Misguided 'Deforms' Demonstrate the Necessity of Judicial Districts*, 73 UMKC L. Rev. 887, 891 (2005).

The net result of the corporate venue statutes was that venue was not limited to where the corporation's registered agent was located, but rather where essentially any agent of the corporation could be found. *See State ex rel. Pagliara v. Stussie*, 549 S.W.2d 900 (Mo. App. 1977) (broadly defining agent under § 508.040 as "a person authorized by another to act for him, one intrusted with another's business" and refusing to restrict the definition to that used in service of process cases).

By 2005, forum shopping had become a substantial problem and one the venue statutes, with their liberal definition of corporate presence, were ill equipped to handle. *See* Craig A. Adoor & Joseph J. Simeone, *The Law of Venue in Missouri*, 32 St. Louis U. L. J. 639, 640 (1988) ("the rules of venue have failed to serve their purpose and have become instead tools for forum shopping"); Darin P. Shreves, *Counselor, Stop Everything! Missouri's Venue Statutes Receive an Expansive Interpretation*, 75 Mo. L.

Rev. 1067, 1067 (2010) ("[A]ttorneys regularly used creative statutory readings and questionable procedural techniques to exploit the state's venue statute and maneuver their lawsuits into favorable forums.").

It is no secret that plaintiffs' attorneys sought venue in St. Louis City due to that forum's "generous juries." *See State ex rel. DePaul Health Ctr. v. Mummert*, 870 S.W.2d 820, 821 (Mo. banc 1994) ("This original action in mandamus is another in a seemingly unending series of extraordinary writ actions in which civil tort plaintiffs and defendants enter protracted procedural plotting to embrace or avoid the generous juries of the City of St. Louis."); Robertson, 73 UMKC L. Rev. at 894 ("[P]laintiffs' attorneys are believed to seek venue vigorously in St. Louis Circuit Court because juries comprised of city residents are typically more sympathetic to plaintiffs and have a reputation for rendering larger verdicts than other jurisdictions."). While the anecdotal evidence of the "generous juries" of St. Louis City is strong, the evidence is not anecdotal only: "the statistics show that the City of St. Louis Circuit Court is the place to be for top verdicts and high settlement figures." *Id.* at 894 (summarizing data between 1994 and 2003).

It is against that background that the Tort Reform Act of 2005 was proposed and eventually passed. The Act worked a drastic change on Missouri's venue statute designed to change the venue laws "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).[8] It was intended to bring "rational guidelines to venue shopping, where a lawyer will choose to try a case in a court for no other reason than the court has a history of awarding the highest settlements." Chad Garrison, *Scott Led Tort Reform Measures Backed By Physicians*, ST. LOUIS BUS. J., Aug. 20, 2003. "The proposed reforms seek to block perceived venue shopping, whereby plaintiffs' attorneys employ statutory venue provisions to file lawsuits in plaintiff-friendly forums." Robertson, 73 UMKC L. Rev. at 887. As then-Governor Blunt, who signed the bill into law, later described it, the Act was designed to "counteract ... 'venue-shopping,' a tactic that involves shifting a case to a friendly court regardless of where the injury occurred." Matt Blunt, Commentary, *How Missouri Cut Junk Lawsuits*, WALL ST. J., Sept. 22, 2009. As described in *Kinsey*, the enactment of § 508.010.5 was intended to "significantly restrict[] venue locales in order to reduce forum shopping by plaintiffs." 394 S.W.3d at 448 n.1. It is not consistent with this legislative intent to interpret the reform of § 508.010.5 to *expand* venue in contradiction of Rule 51.05.

Instead of relying on the traditional venue factors described above (such as a corporation's presence), the Act grounds venue primarily based on the location of the plaintiff's first injury. If the plaintiff's first injury occurred in a foreign jurisdiction, the statute further differentiates between corporate and individual defendants. Unlike prior corporate venue statutes, venue is linked exclusively to the location of the corporate defendant's registered agent. As a result, venue for a corporation was intended to be

[8] http://www.house.mo.gov/content.aspx?info=/bills041/bilsum/commit/sHB1304C.htm.

either the place of injury or the location of the corporate defendant's registered agent. *See generally* David Jacks Achtenberg, *Venue in Missouri After Tort Reform*, 75 UMKC L. Rev. 593 (2007). Unlike the prior venue statute, merely having any agent in the venue is no longer enough; for injuries outside of Missouri, the location of the corporate defendant's registered agent is paramount.

Plaintiffs' attorneys certainly understood the intent of the Act was to drastically restrict forum shopping and curtail the number of lawsuits filed in St. Louis City. *See* Barbara A. Geisman, *Reform or Reshuffle? Consequences of the 2005 Missouri Tort Reform Act*, 42 Wash. U.J.L. & Pol'y 155, 160 (2013) (noting that after the Governor signed the 2005 Act amending the venue statute, lawyers "seeking a plaintiff-friendly venue rushed to file tort claims in the City of St. Louis to beat the Act's effective date of August 28, 2005," and that "3,280 suits were filed in August 2005, compared to the typical average of 400 per month"). The dramatic uptick in lawsuits filed in St. Louis City before the Act became effective is powerful evidence that the plaintiffs' bar understood the intent of the Act at the time—at least until they began to use joinder to attempt to evade it.

Missouri courts interpret statutes in a way that advances the legislative intent of the statute. *See, e.g.*, *Am. Eagle Waste v. St. Louis Cnty.*, 379 S.W.3d 813, 832 (Mo. banc 2010) ("When interpreting statutory law, the court must ascertain the intent of the legislature and give effect to that intent if possible."); *Wallace v. Wallace*, 269 S.W.3d 469, 482 (Mo. App. 2008) ("The seminal rule of statutory construction directs this Court to determine the true intent of the legislature, giving reasonable interpretation in light of

the legislative objective."). Interpreting the venue statute to grant out-of-state plaintiffs venue in the City of St. Louis solely because those plaintiffs strategically collaborate with a City of St. Louis plaintiff to include in their petition does not advance the legislative intent of reducing forum shopping; it does exactly the opposite. It also ignores the significant change in the venue statute from the presence of any corporate agent prior to 2005 to the location of the corporation's registered agent after 2005.

Courts should not interpret statutes in ways that would lead to absurd results. *See, e.g.*, *Aquila Foreign Qualif. v. Dir. of Revenue*, 362 S.W.3d 1, 4 (Mo. banc 2012) ("construction of a statute should avoid unreasonable or absurd results"). The Circuit Court's "joinder creates venue" interpretation of the statute leads to such a result. This case, involving a Minnesota resident injured in Minnesota suing an Illinois corporation in St. Louis, is but one example. There are currently over 9,700 other examples of out-of-state plaintiffs suing out-of-state defendants in St. Louis for injuries that occurred outside Missouri. Such a result is both unreasonable and absurd.

D. Alternatively, Venue in Multi-Plaintiff Cases Should Be Based on the Place Where the Earliest Injury Occurred.

If the Court does not find that Rule 51.01 restricts the use of joinder to extend venue, Abbott respectfully suggests that § 508.010.5 must still apply to restrict venue based on the location where the first injury occurred. In his oft-cited article on the Missouri venue statute, Professor Achtenberg notes that where a multi-plaintiff petition alleges that some plaintiffs were injured in Missouri and some plaintiffs were injured

outside Missouri, the earliest injury alleged in the petition should control the venue analysis.

> [T]he Missouri legislature has mandated[FN] that singular terms in its statutes should be construed as including their plural forms "unless there be something in the subject or context repugnant to such construction."[FN] Under this canon, the two sections must be construed as if they read respectively "in all actions . . . in which the plaintiff [or plaintiffs were] first injured in the state of Missouri" and "in all actions . . . in which the plaintiff [or plaintiffs were] first injured outside the state of Missouri." Construed in this way, the criterion for selecting between the two sections is reasonably clear. Plaintiffs collectively were first injured where the first plaintiff was injured. The court should identify the first injury suffered by any of the plaintiffs and utilize [section] 508.010.4 if that injury occurred in Missouri and [section] 508.010.5 if it occurred outside the state.

Achtenberg, 75 UMKC L. Rev. at 621-22 (first footnote citing § 1.030(2), RSMo (2007)[9]; second footnote citing *BJC Health Sys.*, 121 S.W.3d at 530; remaining footnotes

[9] § 1.030(2), RSMo (2007) states: "When any subject matter, party or person is described or referred to by words importing the singular number or masculine gender, several matters and persons, and females as well as males, and bodies corporate as well as individuals, are included."

omitted).[10]

Under Professor Achtenberg's analysis, St. Louis County was the proper venue for this case because the earliest injury alleged in the petition occurred outside of Missouri. Indeed, while the four Missouri plaintiffs in the petition alleged injuries that occurred in 2007 and 2008, the 20 non-Missouri plaintiffs in the petition included plaintiffs alleging injuries that occurred in 1992, 1994, 1995, 1996, 1997, 2000, 2002, 2003, 2004, 2005, and 2006. (L.F. 142). Because this is a case in which "the plaintiffs" were first injured outside of Missouri, the only potentially proper Missouri venue was St. Louis County.

In reality, however, stopping these abusive venue practices are likely to lead to these cases being filed where they belong—in a state that has some connection to the dispute. If out-of-state, mass tort plaintiffs were not allowed to file their out-of-state disputes in St. Louis City, they would not file them in Missouri at all. After all, plaintiffs' attorneys have not chosen to flood any circuit other than St. Louis City with mass tort cases. These out-of-state cases will not proceed in St. Louis County; they will be dismissed and re-filed in a more appropriate forum related to the dispute of the

[10] On other aspects of the venue statute, the Missouri Supreme Court and the Missouri Court of Appeals have cited Professor Achtenberg's article with approval. *See State ex. rel. Schwarz Pharma, Inc. v. Dowd*, 432 S.W.3d 764, 767 n.3 (Mo. banc 2014); *State ex rel. Audrain Healthcare, Inc. v. Sutherland*, 233 S.W.3d 217, 219 n.3 (Mo. banc 2007); *McCoy*, 366 S.W.3d at 593 n.7 (Mo. App. 2012). Professor Achtenberg does not comment on when joinder of multiple plaintiffs is proper under Rule 52.05.

plaintiffs' choosing. *See* Robertson, 73 UMKC L. Rev. at 904 (suggesting that, upon passage of Tort Reform in 2005, venue shopping "would cease for lack of foundation because plaintiffs would have no procedural basis upon which to choose favorable fora" in Missouri).

E. A Showing of Prejudice Is Not Required, But the Prejudice Is Palpable Nonetheless.

Plaintiff contended below that Abbott would have to show that the Circuit Court's failure to follow the plain language of section 508.010.5 and transfer the case was prejudicial. Not true. Venue is statutory, and a showing of prejudice is not mentioned in the statute. When the Court accepted a post-judgment venue challenge in *Igoe v. Dept. of Labor*, 152 S.W.3d 284 (Mo. banc 2005), it did not conduct a prejudice analysis or one related to convenience. Nor would such an analysis have any grounding in the law because questions of statutory construction are questions of pure law reviewed *de novo*. *See Hervey v. Missouri Dep't of Corr.*, 379 S.W.3d 156, 163–64 (Mo. banc 2012). The construction of a statute should effectuate the policy choice of the legislature, not the competing interests of particular parties to a suit. Once this Court determines that the Circuit Court misinterpreted the venue statute, the analysis should end. Injecting a prejudice inquiry would offend the legislature's considered policy choice about where suits should be brought in this state.

Plaintiff does not contend that a showing of prejudice is required when the trial court rules on a venue motion in the first instance before trial. Nor could Plaintiff, because the venue statute at issue has no such requirement, § 508.010 RSMo., while other

venue statutes in fact do. *See, e.g.*, § 508.330 RSMo. (allowing for change of venue from Marion County upon showing that "inhabitants are prejudiced against the applicant"). When the Missouri legislature intends to require a showing of prejudice, it knows how to do so. It did not do so for venue motions under § 508.010.

It would also be fundamentally unfair to spring a prejudice requirement upon Abbott after trial. The standard should not change merely because the trial court made a mistake in ruling on the motion in the first instance. Abbott preserved the issue for review, and that is all that is required. And, contrary to the Court of Appeals' analysis, it does not matter that the Eastern District and this Court previously denied Abbott's writ applications. (Slip Op. 8). Of course, the denial of a writ has no precedential effect. *State ex rel. Pain, Anesthesia & Critical Care Servs., P.A. v. Ryan*, 728 S.W.2d 598, 601–02 (Mo. App. 1987) ("these denials [of writ petitions] are not to be viewed as decisions on the merits and have no precedential value"); *Augspurger v. MFA Oil Co.*, 940 S.W.2d 934, 937 (Mo. App. 1997) ("The mere denial of a writ does not necessarily reflect any view by this court regarding the merits of the cause, and therefore the doctrine of res judicata does not apply under such circumstances.")

Although no showing of prejudice is required, make no mistake: the Circuit Court's refusal to transfer the case was prejudicial. Plaintiff filed her case in the City of St. Louis and opposed Abbott's motion to transfer venue for a reason—she believed a jury in the City of St. Louis would be more favorable to her claims than a jury in Minnesota or St. Louis County. This is not mere speculation. It is well known that plaintiffs prefer to have their claims tried in the City of St. Louis because they view

jurors there to be more plaintiff-friendly than jurors in other venues. *See State ex rel. Linthicum v. Calvin*, 57 S.W.3d 855, 859 (Mo. banc 2001) (Wolff, J., concurring in part and dissenting in part) (noting that the "preponderance of anecdotal evidence is that jurors in the city of St. Louis are more favorably disposed toward injured plaintiffs' claims than are their counterparts in suburban St. Louis County or in most other counties in the state"). The thousands of out-of-state plaintiffs engineering a way to sue in the City of St. Louis speaks for itself.

Moreover, Plaintiff cannot in good faith say this case would have had the same outcome had it been tried in a different venue. Indeed, in three other Depakote/birth defect cases tried on the merits to date—one in a federal court in Illinois and two in federal courts in Ohio—the juries found for Abbott on all the plaintiffs' claims,[11] whereas in this trial the jury not only found in favor of Plaintiff on compensatory liability, but also rendered a punitive damages verdict $19 million greater than any punitive damages award ever upheld on appeal under the Minnesota punitive damages statute. And it rendered that punitive damages verdict based on evidence that the Circuit Court described

[11] *See In re Depakote*, No. 14-cv-847, 2015 WL 2129313 (S.D. Ill. Mar. 24, 2015); *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-cv-144, 2015 WL 8547598 (S.D. Ohio Nov. 2, 2015); *Z. H v. Abbott Labs. Inc.*, No. 1:14-cv-00176, Dkt. 257 (N.D. Ohio Feb. 2, 2017). Another Depakote/birth defect case in a California state court resulted in a verdict for Abbott because the jury found that the statute of limitations barred the plaintiff's claims.

as "somewhat thin." (A 26, Tr. 1577). In short, although prejudice is not a burden Abbott need carry, it is indisputable here.

* * *

The prejudice is not Abbott's alone, however. The transformation of St. Louis City Circuit Court into a national mass tort docket causes prejudice far beyond the parties in this case. As the Eighth Circuit observed in a recent venue case:

> Administrative difficulties follow for courts when litigation is piled up in congested centers instead of being handled at its origin. Jury duty is a burden that ought not to be imposed upon the people of a community which has no relation to the litigation. In cases which touch the affairs of many persons, there is reason for holding the trial in their view and reach rather than in remote parts of the country where they can learn of it by report only. There is a local interest in having localized controversies decided at home. There is an appropriateness, too, in having the trial of a diversity case in a forum that is at home with the state law that must govern the case, rather than having a court in some other forum untangle problems in conflict of laws, and in law foreign to itself.

K-V Pharm. Co. v. J. Uriach & CIA, S.A., 648 F.3d 588, 597 (8th Cir. 2011) (quoting *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 504, 508–09 (1947)) (alterations in *K-V Pharm*. omitted).

The burden of jury service should not be imposed disproportionately on residents of St. Louis City. *See State ex rel. Linthicum v. Calvin*, 57 S.W.3d 855, 860 (Mo. banc

2001) (Wolff, J., concurring in part and dissenting in part) (describing "tremendously disproportionate burden carried by the citizens of St. Louis city who are called to jury service" and estimating that "nearly 30 percent of the city's 21-and-over population" were summoned to jury service in 2000). Even prior to St. Louis City becoming the national forum of choice for mass-tort plaintiffs, residents of St. Louis City were called for jury service nearly twelve times more than residents of St. Louis County, despite the fact that St. Louis County's population was nearly three times as large. *See* Robertson, 73 UMKC L. Rev. at 900 (summarizing statistics). This thirty-six fold discrepancy cannot help but have a negative long-tail impact on St. Louis City economically and a substantial burden on St. Louis City families. And, with 9,700 plus out-of-state plaintiffs waiting for their day in court, it will get worse.

To prevent these many prejudices—in this case and the thousands of other out-of-state disputes now pending in the City of St. Louis—this Court should interpret the Tort Reform Act as it was written and intended by the legislature. Missouri courts are paid for by Missouri taxpayers to resolve Missouri disputes; Missouri courts are not a federal forum to handle disputes from across the country. Such disputes should be resolved in a local jurisdiction or in federal court using, if appropriate, the multi-district litigation ("MDL") procedure. The MDL procedure, by which federal courts across the country can transfer and consolidate multiple civil actions having common questions of fact, provides significant statutory and procedural protections for plaintiffs and defendants alike and are consolidated for pretrial purposes alone, then transferred back to the transferor courts for trial. *See* 28 U.S.C. § 1407. Missouri has no such procedure or

protections. Nevertheless, the St. Louis City Circuit Court has created a *de facto* and unauthorized MDL, but, unlike the federal MDL, the cases stay put for trial although they have no connection to the venue.

Abbott respectfully requests that the Circuit Court's judgment should be vacated and that Plaintiff's case be remanded. The case should either be transferred to St. Louis County or, more likely, dismissed and re-filed in an appropriate forum with a connection to the dispute.

2. THE CIRCUIT COURT ERRED IN DENYING ABBOTT'S MOTION TO SEVER THE PLAINTIFFS' CLAIMS, BECAUSE (A) THE PLAINTIFFS' CLAIMS DID NOT ARISE OUT OF THE SAME TRANSACTION, OCCURRENCE OR SERIES OF TRANSACTIONS OR OCCURRENCES IN THAT THE PLAINTIFFS' MOTHERS WERE PRESCRIBED DEPAKOTE AT DIFFERENT POINTS IN TIME BY DIFFERENT PHYSICIANS UNDER DIFFERENT CIRCUMSTANCES AND PLAINTIFFS ALLEGED DIFFERENT INJURIES, AND (B) BECAUSE IT WAS IMPOSSIBLE TO CONDUCT A FAIR TRIAL OF ALL THE PLAINTIFFS' CLAIMS IN THAT THERE WERE SIGNIFICANT FACTUAL AND LEGAL DIFFERENCES BETWEEN THOSE CLAIMS.

Abbott is also entitled to reversal of the judgment and remand of the case for further proceedings in St. Louis County because the joinder in this case was improper under Rule 52.05. In this case (and others), the Circuit Court has misused joinder to create what amounts to a national mass-tort docket—effectively an MDL docket without

the authority or procedural protections. And, it did so while ignoring the weight of authority holding that joinder is not permitted merely because the plaintiffs allege injury by the same product. In this case, twenty-four plaintiffs suffering at least seven different types of injuries where the product was subject to different warnings over a nineteen-year period is not the basis for proper joinder.

The interpretation of a procedural rule such as Rule 52.05 is a question of law and is therefore reviewed *de novo*. *See, e.g.*, *Muhm v. Myers*, 400 S.W.3d 846, 849 (Mo. App. 2013). And where "joinder is improper" a "trial court *must* sever upon motion, having *no discretion* to do otherwise." *Guess v. Escobar*, 26 S.W.3d 235, 239 n.3 (Mo. App. 2000) (emphasis added). *See also State ex rel. Gulf Oil Corp. v. Weinstein*, 379 S.W.2d 172, 175 (Mo. App. 1964) ("The permissive joinder of parties is fixed by the Civil Rule. This sets out the law in relation thereto, and the trial court cannot lawfully exercise any discretion contrary to the law relating to the matter before it.").

Rule 52.05, which is derived from Federal Rule of Civil Procedure 20(a),[12] states that separate plaintiffs' claims may be joined only if, *inter alia*, the plaintiffs' right to relief arises "out of the same transaction, occurrence or series of transactions or occurrences." The Circuit Court held this requirement was satisfied solely because each

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[12] *See State ex rel. Nixon v. Dally*, 248 S.W.3d 615, 617 (Mo. banc 2008) (noting Rule 52.05 is derived from Federal Rule 20 and that "the interpretation of a Missouri rule generally should be in accord with the interpretation of the federal rule from which it came").

plaintiff in the petition alleged he or she was "damaged" by exposure to Depakote. (A 7, L.F. 481). The Circuit Court's application of Rule 52.05 was wrong as a matter of law.

A. These Twenty-Four Claims Did Not Arise Out of the Same Transaction, Occurrence or Series of Transactions or Occurrences.

As one Missouri circuit court observed, "[n]umerous courts from around the country have recognized that" the same transaction/occurrence requirement is not met "where the plaintiffs only allege that they took the same drug" and "experienced injuries," because in such cases there are "highly individualized circumstances that characterize each plaintiff's claims." *Ellis v. DePuy Orthopaedics, Inc.*, No. 1116-CV27794, slip. op. at 3 (Mo. Cir. Feb. 9, 2012) (collecting cases); *See also, 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.").

Courts find the same transaction/occurrence requirement is not met in cases such as this one because the plaintiffs have "different medical histories," were "prescribed [the drug] by different physicians under different circumstances" and took the drug "at different points in time." *Cumba*, 2009 WL 1351462, at *1. *See also, e.g., Barton v. Express Scripts, Inc.*, No. 1022-CC10066, slip op. at 3 (Mo. Cir. May 17, 2011) (severing claims where the plaintiffs did "not allege that they received [the drug or its generic equivalent] from the same source, purchased it in the same transaction, were

prescribed [the drug or its generic equivalent] by the same doctors, or suffered identical injuries")[13]; *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 164 F. Supp. 3d 1040, 1049 (N.D. Ill. 2016) ("it is far from clear that plaintiffs' claims—which involve different consumers in different states suffering different injuries after receiving prescriptions from different doctors for a drug used for varying time periods—arise from the same transaction or occurrence"); *Hill v. Eli Lilly and Co.*, No. 1:15-cv-00141, 2015 WL 5714647, at *5-7 (S.D. Ind. Sept. 29, 2015) (plaintiffs' claims against prescription drug manufacturer did not meet the same transaction/occurrence requirement where plaintiffs came from six different states, used the drug for at least four different conditions, and were prescribed the drug by different physicians); *In re Accutane Prods. Liab. Litig.*, No. 8:12-cv-1426, 2012 WL 4513339, at *1 (M.D. Fla. Sept. 20, 2012) (severing plaintiffs in a multi-plaintiff complaint because the "plaintiffs reside in different states, allegedly ingested Accutane at different times, and have allegedly been diagnosed with different adverse reactions to Accutane").[14]

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[13] In *Barton*, the plaintiffs alleged they took a brand-name prescription drug (Reglan) or a generic equivalent. As a practical matter, all plaintiffs took the same drug because federal law requires generic prescription drugs to have the same warnings and same chemical composition as their brand-name counterparts. *See PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011); *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013).

[14] *See also McGrew v. Howmedica Osteonics Corp.*, No. 14-cv-430, 2015 WL 159367, at *2-3 (S.D. Ill. Jan. 13, 2015); *McNaughton v. Merck & Co., Inc.*, No. 04 Civ.

The Court of Appeals did not engage with the numerous cases Abbott cited on this point in its briefing. Rather, the Court cited only two cases from more than fifty years ago for the proposition that "Missouri law clearly allows for the joinder of unrelated plaintiffs who allege injury from the same conduct of the same defendant." (Slip Op. at 6). Neither case—*Kelley v. National Lead Co.*, 210 S.W.2d 728 (Mo. App. 1948), and *Saeger v. Lakeland Development Co.*, 350 S.W.2d 820 (Mo. App. 1961) —speaks to the issue.

Kelley was an action brought by a husband and wife (not unrelated parties) for personal injuries and property damage allegedly caused by fumes of defendant's chemical plant. 210 S.W.2d at 729. While the court notes the action was brought pursuant to the authority of the joinder rule, no party challenged joinder and the court did

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8297, 2004 WL 5180726 (S.D.N.Y. Dec. 17, 2004); *In re Rezulin Prods. Liab. Litig.*, 168 F. Supp. 2d 136, 144-46 (S.D.N.Y. Oct. 16, 2001). At the trial court, Plaintiff incorrectly argued that *In re Prempro Prods. Liab. Litig.*, 591 F.3d 613 (8th Cir. 2010), stands for the proposition that it is proper to join the prescription drug product liability claims of multiple plaintiffs from multiple states. *In re Prempro* does not help Plaintiff because there the Eighth Circuit made clear that it was *not* endorsing the joinder in that case. *See id.* at 623 ("We clarify that we make no judgment on whether plaintiffs' claims are *properly* joined under Rule 20.") (emphasis in original). *See also Barton*, slip op. at 4-5 (L.F. 97-98) (noting that *In re Prempro* did not deal with whether the plaintiffs' claims were "properly joined").

not rule on it. *Id.* It is not hard to understand why. The husband and wife, who jointly owned a home close to the chemical plant, presumably had the same type of exposure from the same conduct of the defendant during the same time period. *Id.*

In *Saeger*, eight investors in the same real estate and business investment gone wrong brought suit against the promoter of the investment. 350 S.W.2d at 821. Again, the investors were hardly unrelated; they all invested in the same project in the same plot of land subject to the same contract. The court found joinder proper because the claims of each of the eight plaintiffs all arose out of the same investment promotion, transfer of land, and contract. *Id.* at 821-822. Neither case supports joinder here.

Holding that merely taking the same drug is enough to satisfy the same transaction/occurrence requirement—notwithstanding that the drug was prescribed at a different time with a different warning based on different information and led to a different injury—would be like holding that all car accident cases involving Ford trucks should be joined together. Of course, the mere commonality of the product at issue is not enough to satisfy the same transaction/occurrence requirement. These plaintiffs do not present the same, or the same series of, transactions or occurrences. Rather, this case impermissibly joins twenty-four plaintiffs suffering at least seven different types of injuries where the product was prescribed to different people suffering different diseases and where the product was subject to different warnings over a nineteen-year period. Each claim here is factually unique.

The Court of Appeals focused on "what information Appellant possessed concerning Depakote's harmful effects, what information Appellant elected to disclose to

physicians and patients about those harmful effects, and what information Appellant was required by law to disclose about the effects." Every one of these facts, however, depends on what Abbott knew at the time each Plaintiff was conceived while his or her mother took Depakote, which differs significantly from case to case.

Because these twenty-four Plaintiffs were born over an eighteen-year period between 1992 and 2010, the facts identified by the Court as common are anything but. Rather than involving the "same conduct," Abbott's knowledge and its conduct changed significantly over time. The information Abbott possessed in 1992 (when the oldest Plaintiff was born) was vastly different than the information it possessed in 2010 (when the youngest Plaintiff was born). Not only did the available information change, but the Depakote Label did as well. In fact, the Court's decision contains a clear inaccuracy: that the Depakote "warning in 1980 remained the same in 2002 despite outdated information" (Slip Op. at 12). In fact, the Depakote Label underwent significant revisions during that time period, including a specific warning regarding spina bifida risk in 1982 and the addition of the Black Box Warning for birth defects in 1996. (L.F. 3146-3177, 3214; Tr. 564; 1102-1103).

Ultimately, each claim is highly individualized, requiring the jury to evaluate Abbott's knowledge, the warning label, the prescribing physician, and the specific injuries, all at the precise time of each Plaintiff's exposure. Twenty-four Plaintiffs over an eighteen year period do not make that possible. Many of these plaintiffs' mothers were prescribed Depakote for different conditions at different times that resulted in different alleged injuries. That is precisely why these cases are being tried on an

individualized basis.

B. The Decision To Hold Individual Trials Demonstrates the Impropriety of Joinder Here.

The factual and legal differences between the twenty-four plaintiffs' claims would have made it impossible to conduct a fair trial involving all of the plaintiffs named in the petition. *See In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, No. 11-3045, 2012 WL 1118780, at *5 (D.N.J. Apr. 3, 2012) (severing plaintiffs in multi-plaintiff complaint and noting, "the factual, temporal, and geographic diversity among Plaintiffs' claims wholly disregards the purposes of permissive joinder because these are claims that no reasonable person would normally expect to be tried together"); *Ellis*, slip op. at 4 (L.F. 103) ("Because pharmaceutical and medical device cases involve highly individualized facts about each plaintiff, it is unrealistic to expect juries to keep the facts straight and render a fair verdict as to each plaintiff.").

For example, because the plaintiffs came from thirteen different states, a single trial would have saddled the jury with the impossible task of applying the law of thirteen different states. Plaintiffs did not provide the Circuit Court with *any* examples of a court conducting a single trial in which the jury was instructed to apply the law of so many different states. The lack of such an example is no surprise. As one court noted in denying a motion to conduct a single pharmaceutical product liability trial with plaintiffs from eleven states, such a trial would "create a nightmare of jury confusion that would be prejudicial to [all parties]." *In re Consolidated Parlodel Litig.*, 182 F.R.D. 441, 447 (D.N.J. 1998).

Moreover, the dates of birth of the twenty-four plaintiffs spanned three decades—the first injured plaintiff born in 1992 and the last injured plaintiff born in 2010. The Depakote Label underwent numerous changes during that period, (*see* L.F. 573, 646-47, 3153), and a drug label that post-dates a plaintiff's injury is generally inadmissible in a pharmaceutical product liability trial because post-injury labels are both irrelevant and unduly prejudicial to the defendant. In fact, in all of the Depakote cases that have been tried to date, including the trial below, the courts excluded Depakote labels that post-dated the plaintiff's injury. *See, e.g.*, *Rheinfrank v. Abbott Labs., Inc.* No. 1:13-cv-144, 2015 WL 5258858, at *3 (S.D. Ohio Sept. 10, 2015); *In re Depakote*, 87 F. Supp. 3d at 924-26; *Z.H. v. Abbott Labs., Inc.*, 2017 WL 57217, at *2-3 (N.D. Ohio Jan. 5, 2017)[15]

[15] Post-injury labels are irrelevant in a failure to warn case because the jury in such a case determines whether the scientific data available *at the time of the plaintiff's injury* warranted a stronger label, and labels that post-date the plaintiff's injury may reflect data that first became available *after* the plaintiff's injury. *See In re Depakote*, 87 F. Supp. 3d at 926 ("Since these labels are based on studies/data not available in 1999, they are not relevant to the adequacy of the 1999 label."). Post-injury labels are also unduly prejudicial because a jury may incorrectly infer that the label must have been inadequate at the time of the plaintiff's injury for no other reason than post-injury labels contain a stronger warning. *See Rheinfrank*, 2015 WL 5258858, at *3 (finding "the probative value of the subsequent labels is substantially outweighed by the danger of unfair prejudice"

For example, while the 2006 Depakote Label would have been the label at issue in a trial of the twin City of St. Louis plaintiffs, that label was inadmissible in this Plaintiff's trial. In short, the varying dates of injury and labels precluded a joint trial of the twenty-four plaintiffs' claims.

The twenty-four plaintiffs also did not all allege they suffered the same injury. For example, while Plaintiff alleged that Depakote caused her to be born with spina bifida (a spinal cord injury), the twin City of St. Louis plaintiffs alleged Depakote caused them to be born with heart injuries. (L.F. 151). Other alleged injuries included, *inter alia*, respiratory problems (plaintiff Brayden Berry); headaches (plaintiff Kennedi Ferdig); deformed hands (plaintiff Karina Koneski); and cleft palate (plaintiff Abigale Riggen). (L.F. 142-52). No jury could be expected to digest the mountains of individualized scientific and medical evidence relevant to each of the plaintiffs and their various alleged injuries and render a reliable verdict. *See Janssen Pharmaceutica, Inc. v. Bailey*, 878 So.2d 31, 48 (Miss. 2004) (holding that trial court erred in conducting a 10-plaintiff pharmaceutical product liability trial where plaintiffs "presented ten unique medical histories" and alleged "a myriad of injuries as a result of this drug").

Indeed, the Circuit Court itself eventually recognized that it was not possible to try all twenty-four cases together. Less than three months after the Supreme Court denied Abbott's writ petition challenging the Circuit Court's rulings on severance and venue, the

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because a "jury presented with [post-injury] labels . . . may conclude that Abbott's earlier labels were inadequate merely because the later labels included expanded warnings").

Circuit Court ultimately agreed that a combined trial could not work. (L.F. 487). In other words, although the Circuit Court denied Abbott's severance and venue motion based on the belief that "any issues of [juror] confusion or improper consideration of evidence can be resolved at trial by effective use of jury instructions," (A 6, L.F. 480), the Circuit Court later reversed itself and determined that jury instructions could not alleviate the prejudice and confusion inherent in a multi-plaintiff trial. The Circuit Court's later determination that the claims of the different plaintiffs in this case are also appropriate for separate appeals under Rule 74.01(b) further emphasizes that these cases are factually and conceptually distinct. The Circuit Court's joinder ruling must therefore also be reversed.

C. The Circuit Court's Failure to Sever Was Not Harmless.

Plaintiff may argue that any error regarding joinder was harmless because the Circuit Court eventually ordered separate trials and thus alleviated any prejudicial aspects of a multi-plaintiff trial. That argument lacks merit. If severance for trial somehow cured error with respect to joinder, then this exception would swallow the rule and the joinder rule would be meaningless. If that was the case, then essentially any claims—no matter how unrelated—could be joined so long as they were separately tried. Of course, Rule 52.05 does not permit such a result. *See State ex rel. Gulf Oil Corp. v. Weinstein*, 379 S.W.2d 172 (Mo. App. 1964) ("The permissive joinder of parties is fixed by the Civil Rule. This sets out the law in relation thereto, and the trial court cannot lawfully exercise any discretion contrary to the law relating to the matter before it.").

Although there is no requirement for Abbot to show prejudice from the trial court's denial of Abbott's severance motion, it too was certainly not harmless. The *only* reason the Circuit Court asserted venue over Plaintiff's claim was its incorrect view that Plaintiff's claim was properly joined with those of the two City of St. Louis plaintiffs. And as discussed in point 1, Abbott was prejudiced as a result of having Plaintiff's case tried in the City of St. Louis.

Abbott also notes that appellate approval of the type of procedural gamesmanship that Plaintiffs employed in this case would sanction the blatant forum shopping that occurred here. That is exactly what the Tort Reform Act was intended to prevent. And it will result in delaying the access of future St. Louis plaintiffs to St. Louis City Circuit Court. When a large number of non-Missouri plaintiffs join their claims with one or two City of St. Louis plaintiffs, chances are that one or more of the non-Missouri plaintiffs will have their day in court before one of the City of St. Louis plaintiffs does.

That is precisely what happened here. When the Circuit Court ordered each side to nominate two plaintiffs for individual trials, the Plaintiffs did not nominate a Missouri resident, let alone a City of St. Louis resident. Instead, they nominated a Minnesota resident as their first choice and a Louisiana resident as their second choice. Abbott's first choice was a City of St. Louis resident, but that plaintiff subsequently dismissed her claims rather than face trial. *See Ground v. Abbott Labs., Inc.*, No. 1122-CC08690 (Mo. Cir. Dec. 31, 2014; Jan. 6, 2015).

Ground, which was combined with this case for trial selection purposes, illustrates the problem and reveals that the sole purpose of some St. Louis plaintiffs is to create

venue for out-of-state plaintiffs. *Ground* involved two child plaintiffs who alleged injuries as a result of their mothers' ingestion of Depakote. One plaintiff was a City of St. Louis resident and the other plaintiff was from Illinois. After Abbott selected the City of St. Louis plaintiff from *Ground* as its first choice for trial, that plaintiff voluntarily dismissed her claims rather than proceed to trial. *See Ground v. Abbott Labs., Inc.*, No. 1122-CC08690 (Mo. Cir. Dec. 31, 2014; Jan. 6, 2015). Abbott subsequently moved to dismiss or transfer the remaining *Ground* plaintiff for improper venue pursuant to Section 508.012. *Ground v. Abbott Labs., Inc.*, No. 1122-CC08690 (Mo. Cir. Feb. 6, 2015). Without a City of St. Louis plaintiff to provide a hook for venue, the remaining plaintiff in *Ground* voluntarily dismissed his case rather than face transfer to St. Louis County. *See Ground v. Abbott Labs., Inc.*, No. 1122-CC08690 (Mo. Cir. Feb. 16, 2015). Nine days later, he re-filed his case in his home state of Illinois. *Jackson v. Abbott Labs., Inc.*, No. 3:15-cv-0186 (S.D. Ill. Feb. 25, 2015).

Ground is not the only instance in which plaintiffs use joinder when it serves their purposes, but disavow joinder and seek severance when it does not. In this case, after Plaintiff obtained her verdict, she moved for a Rule 74.01(b) judgment, effectively divorcing her case from that of the other twenty-three plaintiffs. As a result, these twenty-four plaintiffs, whose claims allegedly arose out of the same transaction, occurrence or series of transactions or occurrences, will have piecemeal trials *and* piecemeal appeals. No efficiencies are gained. The idea of joinder in these cases is a fiction written solely to enable venue in St. Louis City.

And that is just the impact in a single case. Although some have surmised that potential future Missouri plaintiffs are benefited by making this state's courts a magnet for out-of-state plaintiffs, *see State ex rel. Wyeth v. Grady*, 262 S.W.3d 216, 227 (Mo. banc 2008) (Clark, Senior Circuit Court Judge sitting by designation, concurring), the volume of cases employing these procedural shenanigans demonstrates that many St. Louis residents will be waiting for years—and perhaps more than a decade—to have their disputes heard. Missouri plaintiffs are actually harmed by forum-shopping-inspired misjoinder maneuvers because those maneuvers put their cases on the back burner while Missouri courts and juries hear out-of-state plaintiffs' cases.

In short, the Circuit Court erred in denying Abbott's severance motion, and that error prejudiced Abbott. As a result, this Court should vacate the judgment and remand the case with a mandate that the Plaintiff's claims be severed.[16]

3. THE CIRCUIT COURT ERRED IN DENYING ABBOTT'S MOTIONS FOR DIRECTED VERDICT AND JUDGMENT NOTWITHSTANDING THE VERDICT ON PLAINTIFF'S FAILURE TO WARN CLAIM BECAUSE THE DEPAKOTE LABEL WAS ADEQUATE AS A MATTER

[16] The Circuit Court also erred in denying Abbott's motion to dismiss on *forum non conveniens* grounds. (*See* L.F. 64, 475). If this Court remands the case for further proceedings, Abbott reserves its right to move to dismiss the case for lack of personal jurisdiction, *see Daimler AG v. Bauman*, 134 S.Ct. 746 (2014), or in the alternative, on *forum non conveniens* grounds, so that the claims can be pursued in an appropriate forum.

OF MINNESOTA LAW IN THAT THE LABEL (A) ATTRACTED THE ATTENTION OF THOSE TO WHOM IT WAS DIRECTED, (B) EXPLAINED THE MECHANISM AND MODE OF INJURY, AND (C) EXPLAINED HOW TO SAFELY USE THE PRODUCT TO AVOID INJURY.

If this Court rejects Abbott's venue and joinder arguments, it should nevertheless reverse the judgment and direct the Circuit Court to enter judgment for Abbott because the Circuit Court erred in denying Abbott's motions for directed verdict and judgment notwithstanding the verdict. A denial of such motions is reviewed *de novo.* *Ellison v. Fry*, 437 S.W.3d 762, 768 (Mo. banc 2014). And although the evidence is viewed "in the light most favorable to the verdict," *id.*, a trial court's judgment "is afforded no deference when the law [applicable to the plaintiff's claim] has been erroneously declared or applied," *Info. Techs. v. St. Louis Cnty.*, 14 S.W.3d 60, 62 (Mo. App. 1999).

A. Abbott's Warning Was Adequate as a Matter of Minnesota Law.

Plaintiff agrees that Minnesota substantive law governs here. A warning is adequate as a matter of Minnesota law when it: "(1) attract[s] the attention of those [to whom it is directed][17]; (2) explain[s] the mechanism and mode of injury; and (3)

[17] Plaintiff also agrees that Minnesota follows the learned intermediary doctrine in prescription drug cases; so Abbott had a duty only to warn prescribing physicians, not patients. *See, e.g., Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 n.1 (Minn. 1970) ("The manufacturer has no duty to warn the lay public regarding prescription drugs.").

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). The Depakote Label at issue in this case was adequate as a matter of Minnesota law because it met all three of the Minnesota requirements for adequacy of a warning.

First, a Black Box Warning is by definition one that "attract[s] the attention of" prescribing physicians. Plaintiff's own warnings expert, Dr. Blume, testified that a "black box is considered the most identifying form of a warning" because it "is information that's at the top of the [label] in a black kind of rectangular box" and "is meant to catch the eye" and "the interest of the reader." (Tr. 1035). Dr. Blume also agreed that a Black Box Warning "is the most serious type of warning mandated by the U.S. Food and Drug Administration," is "considered the strongest labeling form," "is prominently featured in the labeling of drugs to warn prescribers about serious adverse reactions," and "is the most significant way to stress a warning or safety information about a drug." (Tr. 1082-83). Indeed, Missouri courts also have recognized the significance of a Black Box Warning. *See Franzman v. Wyeth LLC*, 451 S.W.3d 676, 681 (Mo. App. 2014) (noting a "black-box warning" is "the strongest form of warning the FDA requires"); *Huelskamp v. Patients First Health Care, LLC*, 475 S.W.3d 162, 166 n.2 (Mo. App. 2014) (noting a Black Box Warning informs "health care providers there is an important safety concern with a medication which is sufficient to cause real concern about injury or death"). Here, Dr. Jacoby read and knew the contents of the Depakote warning, knew about the spina bifida incidence rate in the warning, and knew that

Depakote was rated as a Category D drug. (Tr. 1213-17, 1454-55). There is no question the warning here "attract[s] the attention of" prescribing physicians.

Second, the Black Box Warning explains the "mechanism and mode of injury" at issue—spina bifida. The Black Box Warning states clearly that Depakote can cause neural tube defects, such as spina bifida. Of course, trained physicians are presumed to understand medical terms. And Dr. Jacoby—the learned intermediary here—testified that the neural tube is a tube from which the spinal cord forms during gestation, and a defect in that formation from neural tube to spinal cord is called spina bifida. (Tr. 1207). He also testified that spina bifida can have a number of serious and permanent consequences. (Tr. 1236). In fact, Dr. Jacoby also testified that when he prescribed Depakote to Ms. Vititoe, he "explained to her about neural tube defects and how they worked and what we're worried about and why they can be serious." (Tr. 1240). As a result, both the physician and the patient understood the "mechanism and mode of injury."

Third, the only ways to "avoid" the possibility of the "injury" at issue in this case—spina bifida from Depakote—is to either avoid the use of Depakote during pregnancy or avoid getting pregnant while on Depakote. And the Black Box Warning clearly makes that point. (*See* A 16, L.F. 3195) (stating that because Depakote can cause spina bifida "the use of Depakote tablets in women of childbearing potential requires that the benefits of its use be weighed against the risk of injury to the fetus.")). Indeed, there was a period of time before Ms. Vititoe began seeing Dr. Jacoby that she chose to not take Depakote because she was considering getting pregnant. (Tr. 1277 ("Q. From this

record it looks like the reason she went off Depakote and switched to Lamictal is because she wanted to get pregnant in the future? A. I believe so, yes."); L.F. 3259 (medical record stating "she had no trouble with Depakote, but apparently if she got pregnant, did not want to be on Depakote")). And when Dr. Jacoby put Ms. Vititoe back on Depakote, his record noted that Ms. Vititoe "understands that she should not get pregnant on this medication because of the risk of neural tube defects." (L.F. 3268).

Plaintiffs will claim that Dr. Jacoby's testimony—that he would not have prescribed Depakote if he had been provided with additional information about comparative risk (Tr. 1315-16)—proves that the warning was inadequate. But Dr. Jacoby's subjective, hindsight testimony about what he would have done had the warning been phrased differently, while perhaps relevant to the issue of causation, does not change the law regarding the adequacy of warnings. Whether a warning is legally adequate is an objective standard, not a subjective one. *See, e.g., Kelso v. Bayer Corp.*, 398 F.3d 640, 642 (7th Cir. 2005); *Knowlton v. Deseret Med., Inc.*, 930 F.2d 116, n. 3 (1st Cir. 1991). Plaintiffs may also attack the warning for other reasons. But those criticisms are irrelevant because Dr. Jacoby did not testify that any other change in the warning would have changed his decision to prescribe Depakote.

In short, Abbott was entitled to judgment as a matter of law because the Depakote Label met all three of the controlling Minnesota requirements for adequacy of a warning.

B. Minnesota Law Has Never Imposed a Duty To Specifically Warn of Comparative Risks of Alternative Products.

In denying Abbott's motions for directed verdict and judgment notwithstanding the verdict, the Circuit Court accepted Plaintiff's argument that even though the Depakote Label included a Black Box Warning about spina bifida, the label did not meet the Minnesota standard for adequacy because Abbott also had a duty to warn that Depakote's overall risk for all birth defects was higher than that of all other AEDs on the market and therefore Depakote should be used in women of childbearing potential only if all other AEDs failed to control the woman's seizures. Plaintiff cannot point to any Minnesota state court decision holding that a manufacturer has a duty to warn about how its own product's risks compare to those of other manufacturers. *Cf. In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161, 1165 (8th Cir. 2013) (declining to affirm that comparative warning theory was viable under Minnesota law and instead affirming on alternative theory). If the law of Minnesota is to be expanded to required comparative warnings, it should be up to the Minnesota, not Missouri, courts to do so.

Through her lawsuit, Plaintiff is asking the Missouri courts to *expand* Minnesota state law.[18] But as federal courts routinely recognize, expansion of a state's law should

[18] An expansion in Minnesota law requiring warnings of relative risk would have endless and unintended consequences. Manufacturers of ladders would have to distinguish between the relative risk of their models and warn accordingly. Car manufacturers would need to warn about the relative risk of cars with different types of

occur only through that state's courts. *See, e.g., Ashley Cnty. Ark. v. Pfizer, Inc.*, 552 F.3d 659, 673 (8th Cir. 2009) ("It is not the role of [this court] to expand state law in ways not foreshadowed by state precedent."); *Insolia v. Philip Morris Inc.*, 216 F.3d 596, 607 (7th Cir. 2000) ("Innovative [Wisconsin] state law claims should be brought in [Wisconsin] state court.").

Federal courts follow this rule because allowing plaintiffs to expand a state's law through an end-run of that state's courts encourages yet more forum shopping and leads to inequitable administration of a state's laws. *See MHR Corp. v. Robin*, 687 F. Supp. 1257, 1258 (N.D. Ill. 1988) (noting that under the United States Supreme Court's *Erie* doctrine, a novel theory of a state's laws should be brought in that state's courts); *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 428 (1996) (noting the "twin aims" of the *Erie* doctrine are "discouragement of forum-shopping and avoidance of inequitable administration of the laws"). And an aberrant interpretation of Minnesota law is much more likely to be corrected on appeal or by appropriate legislation if the decision issues from a Minnesota court.

This Court should also decline to expand another state's laws. After all, Missouri courts also recognize that forum shopping and inequitable administration of another

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safety devices or even different types of cars (small vs. large, fast vs. slow, convertible vs. hardtop). To hold that a warning of the absolute risk is not sufficient is a holding that cannot be contained to pharmaceutical product liability cases. It would have a substantial and unwarranted impact on manufacturers of all types.

state's laws are disfavored practices. *See State ex rel. Old Dominion Freight Line, Inc. v. Dally*, 369 S.W.3d 773, 780 (Mo. App. 2012) (rejecting a plaintiff's argument because that argument "might encourage forum shopping"); *State ex rel. Gannon v. Gaertner*, 592 S.W.2d 214, 215-16 (Mo. App. 1979) (similar); *State ex rel. Dykhouse v. Edwards*, 908 S.W.2d 686, 689-90 (Mo. banc 1995) (noting that the rule of comity—the decision of one state's courts to defer to another state's policies—"promote[s] uniformity" in the application of the other state's laws).

This is particularly true in the context of the venue and joinder arguments that Abbott raises above. *If* Missouri courts will be allowed to remain nationwide magnet courts for resolving lawsuits between out-of-state plaintiffs and out-of-state defendants involving entirely out-of-state conduct resulting in entirely out-of-state injuries, then the least they can do is abide by the controlling state's existing laws, lest Missouri become the source of upheaval in its 49 sovereign sister states' laws.

While Plaintiff may identify some states' courts outside Minnesota endorsing the theory that a manufacturer has a duty to warn about its product's risks compared to those of other manufacturers, many courts have rejected that theory.[19] Even if this Court were

[19] *See, e.g., Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990) ("The manufacturer is obligated to make a reasonable disclosure of all the risks inherent in its own drug. It is not obligated to provide a comparison of its drug with others."); *Smith v. Wyeth Labs., Inc.*, No. Civ.A. 84-2002, 1986 WL 720792, at *10 (S.D. W.Va. Aug. 21, 1986) (rejecting plaintiffs' "argument that a drug manufacturer may be required to

to find it *possible* that the Minnesota Supreme Court would adopt such a comparative risk theory, it would be inappropriate for this Court to expand Minnesota law without guidance from Minnesota. *See Tucker v. Paxson Mach. Co.*, 645 F.2d 620, 625 (8th Cir. 1981) (refusing to apply novel product liability theory to a case governed by Missouri law because the few courts outside of Missouri to address the legitimacy of that theory had "reached different conclusions"). *See also, e.g.*, *Travelers Indem. Co. v. Dammann & Co., Inc.*, 594 F.3d 238, 253 (3d Cir. 2010) ("Where two competing yet sensible interpretations of state law exist, we should opt for the interpretation that restricts liability, rather than the one that expands it, until the [relevant state supreme court] decides differently."); *Insolia*, 216 F.3d at 607 ("When confronted with a state law question that could go either way, the federal courts usually choose the narrower interpretation that restricts liability."); *In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161, 1165 (8th Cir. 2013) (declining to affirm that comparative warning theory was viable under Minnesota law and instead affirming on alternative theory).

Plaintiff may argue that even if Minnesota does not place a general duty on manufacturers to provide a comparative warning, Abbott assumed that duty because the

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represent that other drugs with similar effects are safer"); *Pluto v. Searle Labs.*, 690 N.E.2d 619, 620-21 (Ill. App. 1997) (rejecting argument that the manufacturer of an intrauterine birth control device ("IUD") had a duty to warn physicians that users of the device had a higher risk of contracting a sexually transmitted disease or pelvic inflammatory disease than did users of other forms of birth control).

2002 Depakote Label was somehow misleading in saying that there was a "possible similar association" with the use of other AEDs:

> 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 PHENOBARBITOL, REPORTS INDICATE A POSSIBLE SIMILAR ASSOCIATION WITH THE USE OF OTHER ANTIEPILEPTIC DRUGS

(A 19, L.F. 3198). Plaintiff misreads the label. A "possible similar association" indicates that Depakote also "results in an increased incidence of birth defects in the offspring." It does not state that the degree of risk is identical; it simply says that there is a similar type of risk. No witness testified that the Depakote Label was misleading. Moreover, Plaintiff's argument ignores that Depakote was the only AED on the market in 2002 that contained a Black Box Warning for birth defects *and* that the Depakote Label included a "Category D" pregnancy rating. Plaintiff's own labeling expert, Dr. Blume, testified that a Category D rating means that the drug is less safe than drugs with a Category C rating and that a Black Box Warning is the strongest labeling form and the most significant way to stress a warning about a drug. (Tr. 1084-1085, 1082-83).

Therefore, although Abbott disputes that it had it had a duty to provide a comparative warning, these critical distinctions between Depakote's label and the labels

of other AEDs provided prescribing physicians a clear comparison. And it was a comparison of which prescribing physician Dr. Jacoby, and Plaintiff's mother, were well aware. (Tr. 1189-90, 1277-79 (Ms. Vititoe believed Lamictal posed a lesser risk of birth defects than Depakote); Tr. 1280 (Dr. Jacoby acknowledging that Ms. Vititoe had switched from Depakote to Lamictal because of the teratogenic potential of Depakote relative to Lamictal)). Dr. Jacoby's subjective, hindsight testimony about what he would have done had the warning been phrased differently cannot change Minnesota law regarding the objective adequacy of warnings. This is particularly so when, to a learned intermediary, the fact that Depakote was the only AED to carry a Black Box Warning and to be classified as category D conveyed its comparative teratogenic risk to all other AEDs.

C. The Analysis of the Court of Appeals Is Riddled with Inaccuracies.

In affirming the Circuit Court's decision, the Court of Appeals adopted Plaintiff's arguments regarding the adequacy of the Depakote Label without verification of the facts Plaintiff offered to support them. For example, the Court of Appeals stated that Abbott's "warning in 1980 remained the same in 2002 despite outdated information," then points to a *single* sentence in the ten-paragraph Warning section of the Depakote Label that was unchanged. In fact, the Depakote Label underwent significant revisions between 1980 and 2002 regarding teratogenic risks, including most notably the addition of a prominent Black Box Warning calling attention to Depakote's teratogenic risks generally and the risk of spina bifida specifically—a warning not contained in any other AED label.

The Court of Appeals also stated that Abbott's label was inadequate or inaccurate because Abbott "knew of multiple studies concluding that…the risk of spina bifida was significantly higher than the 1-2 percent stated in the label." But the fact that "studies" might have existed does *not* necessarily impose a duty on Abbott to include those studies or their findings in the Depakote label. Studies with conflicting conclusions on the same topic are commonplace in scientific research, and drug manufacturers and the FDA work together to evaluate such studies for scientific reliability and ensure that prescribing physicians are presented with information that is scientifically established. Plaintiff's expert Dr. Oakley testified that even today, 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). Abbott's 2002 label cannot be faulted for warning of the same percentage of risk adopted by Plaintiff's expert.

The Court of Appeals further noted that Abbott's duty to provide adequate warnings under Minnesota law included a duty to test its product, implying that the jury could have found that Abbott breached its duty because it "conducted no independent research or studies to evaluate Depakote's safety in pregnancy." But Minnesota law does not recognize a separate cause of action for failure to test a product. "If the manufacturer designs the product safely, manufactures the product safely, and provides an adequate warning of dangers inherent in the use of the product, then a failure to test the product cannot, standing alone, cause any injury." *Kociemba v. G.D. Searle & Co.*, 707 F.Supp. 1517, 1527-28 (D. Minn. 1989).

Finally, evidence regarding Abbott's internal sales goals or marketing strategy has no bearing on the adequacy of the Depakote Label as written. Respectfully, the Court of Appeals Opinion's extensive discussion of Abbott's internal marketing discussions, drawn directly from Plaintiff's brief, is the result of cherry-picking from hours of testimony and thousands of pages of documents. More importantly, it is not relevant to the issue of the label's adequacy. Whether the Depakote Label adequately warned prescribing physicians is not dependent upon Abbott's motives or sales goals; it is an objective standard. Even more, there is no evidence that Dr. Jacoby received or relied on any marketing materials or sales representatives in making his prescribing decision, and therefore any sales goals or marketing strategies could not be causally related to the alleged injuries in this case.

* * *

Abbott's warning was not inadequate. Dr. Jacoby's testimony among others confirmed that the Black Box Warning here: "(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*, 676 N.W.2d at 274. Both Dr. Jacoby and Plaintiff's mother knew that Depakote increased the risk of birth defects, and particularly of spina bifida. Not all tragedies can be prevented by a warning; this one falls in that category. To hold otherwise would dramatically expand potential liability in failure to warn cases and cement Missouri's place as the forum of choice for plaintiffs across the country who seek to escape application of their own state's laws.

4. THE CIRCUIT COURT ERRED IN DENYING ABBOTT'S MOTIONS FOR DIRECTED VERDICT AND JUDGMENT NOTWITHSTANDING THE VERDICT ON PLAINTIFF'S DEMAND FOR PUNITIVE DAMAGES BECAUSE PLAINTIFF DID NOT PRESENT CLEAR AND CONVINCING EVIDENCE THAT ABBOTT DELIBERATELY DISREGARDED THE RIGHTS AND SAFETY OF OTHERS IN THAT ABBOTT WARNED PRESCRIBING PHYSICIANS OF DEPAKOTE'S RISK OF SPINA BIFIDA VIA A BLACK BOX WARNING AND ABBOTT DID NOT HAVE FAIR NOTICE UNDER THE DUE PROCESS CLAUSE THAT COMPARATIVE WARNINGS WERE REQUIRED UNDER MINNESOTA LAW.

Even if the judgment for compensatory damages is affirmed, the Court should apply *de* novo review and vacate the punitive damages award as inconsistent with Minnesota law, as evidenced by the Eighth Circuit's indistinguishable analysis and interpretation of Minnesota law in a nearly-identical comparative risk case. Such an award is also inconsistent with the Due Process Clause as Abbott did not have any notice, much less the fair notice required, that the type of comparative warning at issue was required under Minnesota law. No appellate court *ever* has imposed punitive damages for failure to warn of a danger when the warning in fact was contained in a Black Box Warning. A Missouri court attempting to apply Minnesota law should not be the first.

A. Abbott Did Not Act with Deliberate Disregard.

The Minnesota legislature has restricted punitive damages to cases where the plaintiff establishes by "clear and convincing evidence" that the defendant acted with a

"deliberate disregard for the rights or safety of others." Minn. Stat. Ann. § 549.20. By enacting the punitive damages statute, the Minnesota legislature intended "to limit the frequency and amounts of punitive damages awards." *Lewis v. Equitable Life Assur. Soc. of the U.S.*, 389 N.W.2d 876, 891 (Minn. 1986). *See also J.W. ex rel. B.R.W. v. 287 Intermediate Dist.*, 761 N.W.2d 896, 904 (Minn. App. 2009) (noting that under Minnesota law, punitive damages are an "extraordinary remedy" that are permitted only "with caution and within narrow limits").

Here, Plaintiff offered no evidence, let alone "clear and convincing evidence," that Abbott acted with a "deliberate disregard for the rights or safety of others." To the contrary, Abbott expressly warned about the risk of spina bifida—the very injury suffered here—and did so in a Black Box Warning that the learned intermediary, Dr. Jacoby, in fact read and understood. Plaintiff's own warnings expert agreed that a Black Box Warning "is the most serious type of warning mandated by the U.S. Food and Drug Administration," is "considered the strongest labeling form," and "is the most significant way to stress a warning or safety information about a drug." (Tr. 1082-83).

The inclusion of a Black Box Warning about the exact injury at issue is the *opposite* of a "deliberate disregard for the rights or safety of others." Plaintiff can point to no other appellate court—*from Minnesota or anywhere else*—holding that inclusion of a Black Box Warning about the exact injury at issue constitutes a deliberate disregard for the rights or safety of others. Rather, the Eighth Circuit, applying the same Minnesota punitive damages statute, held that even a drug label warning *less prominent* than a Black Box Warning precludes an award of punitive damages under Minnesota law because a

drug manufacturer that warns about its drug's risk cannot be found to have deliberately disregarded that risk.

B. This Court Should Follow the Eighth Circuit's Interpretation of Minnesota Law.

In *In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161 (8th Cir. 2012), the plaintiff alleged that a drug manufacturer failed to adequately warn that the drug could cause ruptures of the Achilles tendon when taken in combination with corticosteroids. The drug's label did not include a Black Box Warning about that risk, but instead included a less prominent and less strong warning about that risk in the last paragraph of the label's ten-paragraph "Warnings" section. *Id.* at 1164. The district court upheld the jury's award of punitive damages, but the Eighth Circuit, applying Minnesota law, reversed that decision. The court held that even though a reasonable jury could find that the manufacturer was negligent in not doing more to warn physicians about the risk, punitive damages were not warranted because the inclusion of the warning in the last paragraph of the ten-paragraph warnings section was inconsistent with a finding that the manufacturer deliberately disregarded the risk.

> As a matter of law, the record evidence failed to establish [that the defendant] OMJP deliberately disregarded the risk of tendon injuries in elderly patients taking corticosteroids, as required for punitive damages under Minnesota law. By warning of that risk in the package insert, OMJP actively sought ways to prevent the dangers associated with its product.

> The 2001 warning was also published in the PDR, a reference widely used by physicians.
>
> * * *
>
> The evidence is neither clear nor convincing, as a matter of law, that OMJP deliberately disregarded the safety of the users of Levaquin. The district court erred in denying JMOL for OMJP on punitive damages.

Id. at 1169-70.

In re Levaquin is indistinguishable from the case at hand, except that the Depakote Label contained an *even stronger* and *more prominent* warning of the risk of the injury at issue than did the label at issue in that case. Abbott warned of the risk of the spina bifida injury suffered by Plaintiff, not only in the "Warnings" section of the label as in *In re Levaquin*, but also in the Black Box Warning featured prominently at the front of the label. In affirming the punitive damages award, the Court of Appeals ignored entirely the Eighth Circuit's reasoned analysis and interpretation of the applicable Minnesota law set forth in *In re Levaquin*, a remarkably apposite decision. This Court should follow the Eighth Circuit's interpretation of Minnesota law for two reasons.

Because the Eighth Circuit encompasses Minnesota, the Eighth Circuit is considered an expert on Minnesota law and therefore its interpretations of Minnesota law are not only entitled to consideration, but also "great deference" by non-Minnesota courts. *See, e.g.*, *Pembaur v. City of Cincinnati*, 475 U.S. 469, 484 n.13 (1986) ("We generally accord great deference to the interpretation and application of state law by the courts of appeals [that encompass that state]."). Other federal appellate courts would

defer to the *Levaquin* opinion, unless convinced that the Eighth Circuit had "disregarded clear signals emanating from [Minnesota's] highest court pointing to a different rule." *Mellon Bank, N.A. v. Ternisky*, 999 F.2d 791, 796 (4th Cir. 1993). *See also, e.g., In re Dow Corning Corp.*, 778 F.3d 545, 548-49 (6th Cir. 2015) ("We usually defer to our sister circuits' analyses of the law of the states within their respective borders.") (internal quotation marks omitted) (collecting cases from multiple federal circuits).

Deference to a home circuit's application of state law provides uniformity and discourages forum shopping. *See, e.g.*, *Abex Corp. v. Md. Cas. Co.*, 790 F.2d 119, 125 (D.C. Cir. 1986) (deferring to Second Circuit's interpretation of New York law and noting it was "obvious" that the plaintiffs had filed their case in the District of Columbia because the Second Circuit's interpretation of New York law was favorable to the defendant). Here, in incorrectly applying Minnesota law on punitive damages and failing to follow *In re Levaquin*, the Circuit Court's decision has the inadvertent effect of allowing recovery of punitive damages in Missouri where they would not be allowed in Minnesota, thereby encouraging Minnesota plaintiffs to sue in Missouri rather than in their home state, and exacerbating the fundamental problem with joining thousands of out-of-state plaintiffs with a handful of plaintiffs from the City of St. Louis.

Moreover, numerous other courts around the country, applying punitive damages standards similar to Minnesota's, have held that a manufacturer that warns about the risk at issue cannot be held liable for punitive damages even if a jury could find for plaintiff on the underlying compensatory failure to warn claim. *See Heston v. Taser Int'l, Inc.*, 431 F. App'x 586, 589 (9th Cir. 2011) (punitive damages claim failed as a matter of law

under the conscious disregard standard where defendant "made efforts, albeit insufficiently, to warn its customers about the risks posed by" the product); *Dudley v. Bungee Int'l Mfg. Corp.*, No. 95-1204, 1996 WL 36977, at *3-4 (4th Cir. Jan. 31, 1996) (plaintiff's punitive damages claim failed as a matter of law under the conscious disregard standard because the product packaging, "at least in general terms, warned others of the" potential "dangers" at issue); *Toole v. McClintock*, 999 F.2d 1430, 1433, 1435-36 (11th Cir. 1993) (plaintiff's punitive damages claim failed as a matter of law under the conscious disregard standard because the "manufacturer took steps to warn" about the risk); *Krister v. Beech Aircraft Corp.*, 479 F.2d 1089, 1096-97 (5th Cir. 1973) ("[t]he fact that the" manufacturer took "steps to inform" plaintiff "of potential danger absolved" manufacturer of liability for punitive damages under the conscious indifference standard); *Salvio v. Amgen, Inc.*, No. 2:11-cv-00553, 2012 WL 517446, at *7-8 (W.D. Pa. Feb. 15, 2012) (drug manufacturer could not be held liable for punitive damages under the conscious disregard standard where its drug's label warned of the "very injury" at issue in the case); *In re Fosamax Prods. Liab. Litig.*, 924 F. Supp. 2d 477, 490 (S.D.N.Y. 2013) (no jury could find that the manufacturer "'consciously disregarded' the safety of others" where the label warned about the injury at issue); *Ilosky v. Michelin Tire Corp.*, 307 S.E.2d 603, 619 (W. Va. 1983) (manufacturer was entitled to judgment on demand for punitive damages because the manufacturer "had taken steps to warn" about the risk at issue).

Were this Court to predict that Minnesota law permits a drug manufacturer to be held liable for punitive damages under a deliberate disregard standard *even when* the

manufacturer uses a Black Box Warning about the very risk at issue, this Court would be predicting that Minnesota is an outlier in the field of punitive damages law. Plaintiff can point to no basis upon which this Court could—or should—make such a prediction about another state's laws.[20]

C. Abbott Did Not Have Fair Notice that Its FDA-Approved Warning Label Violated Minnesota Law.

While *Wyeth v. Levine*, 555 U.S. 555 (2009), preserved a dual federal and state regulatory scheme for drug labeling, the ability of states to regulate labeling, particularly through punitive tort damages, is not unlimited. Where a defendant complies with federal labeling requirements, as Abbott did, it should only be liable for punitive damages for failure to comply with more stringent state standards when the state has provided clear notice of what its standards require. Minnesota law has not provided such notice.

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[20] In the Circuit Court, Plaintiff argued that her demand for punitive damages is supported by *Hodder v. Goodyear Tire & Rubber Co.*, 426 N.W.2d 826 (Minn. 1988), but that case held that the evidence was sufficient to support a punitive damages award because the jury could have found "Goodyear's inadequate *distribution* of K-rim warnings was willfully indifferent." *Id.* at 835 (emphasis added). Here, however, Plaintiff's theory was not that Abbott failed to adequately distribute the Depakote warning. Nor could that be Plaintiff's theory, as it is undisputed that the prescribing physician, Dr. Jacoby, actually received and read the warning before prescribing Depakote to Ms. Vititoe. (Tr. at 1210).

Indeed, Minnesota has not provided any notice at all that comparative warning of the type at issue here are required at all. Without such notice, punitive damages may not be imposed consistent with the Due Process Clause. *See* U.S. Constitution, Amend. V, XIV; Minn. Constitution Art. I, § 7.

States may not regulate warning labels via punitive damages in a way that violates due process because the award comes without warning and imposes exceptionally severe fines, particularly on the "somewhat thin" evidence here. Imposing a punitive award in such a situation exceeds the "due process standards that every award must pass." *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 501 (2008). The Supreme Court has made clear that "[e]lementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose. " *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996).

The award here was imposed without warning and the severity of the award is unprecedented under Minnesota law. *State Farm* and *BMW v. Gore* stand for the proposition that the Due Process Clause requires a defendant to be on notice "that punitive damages may attach to certain conduct, and to notice of the size of the potential award." *Heil Co. v. Evanston Ins. Co.*, 690 F.3d 722, 729 (6th Cir. 2012). The punitive damages award here came with no warning: it was imposed by a *Missouri* court relying on an unprecedented and ill-considered interpretation of *Minnesota* law that contravenes the *federal* determination that Depakote's warning struck the appropriate safety

balance. Abbott had no way to know that it would be liable for punitive damages under a failure to warn theory when it distributed an FDA-approved warning.

This is not a case in which a state legislature imposed additional warning requirements by statute. Rather, this is a case where this lawsuit alleged that Abbott did not utilize the particular type of warning that Plaintiff's counsel advocates. Second guessing a label more than a decade after the fact is not fair notice. Abbott could not have foreseen that a Missouri court would interpret Minnesota law in this way nor that a Missouri court would impose liability for the first time under Minnesota law for failure to warn of the precise injury about which Abbott warned. There is a reason why this is the first known case where an appellate court upheld a punitive damages award for failure to warn of a risk described in a Black Box Warning. That is because to allow punitive damage here would violate basic principles of Due Process.

Imposing such a significant award based on a novel theory of liability—a theory of which Abbott had no notice until it faced this substantial fine—upends the purpose for which punitive damages are imposed. Punitive awards are designed to "punish the defendant and to deter him, and others like him, from *intentional wrongs* and *deliberate disregard* of the safety or rights of others." *Rosenbloom v. Flygare*, 501 N.W.2d 597, 602 (Minn. 1993) (emphasis added); *see also Baker*, 554 U.S. 471, 492 & n.9 (2008) (collecting cases). A punitive award thus requires a finding of liability based on heightened culpability. *See Molenaar v. United Cattle Co.*, 553 N.W.2d 424, 429 (Minn. App. 1996) ("The focus lies on the defendant's wrongful conduct that must be deterred, not the specific outcome of the conduct.").

A defendant that expressly complies with stringent federal labeling mandates without notice of heightened state law requirement cannot be held liable under this heightened standard, particularly in light of the severity of this award. To hold otherwise violates due process.

D. Plaintiff's Evidence Is Not Relevant to Her Theory of Liability.

At trial, Plaintiff offered various criticisms of Abbott's conduct with regard to Depakote. For example, during jury arguments Plaintiff said that Abbott should not only have warned that Depakote had a higher rate of birth defects than all other AEDs, but that Abbott should have also warned that Depakote's rate of birth defects made it one of the three most teratogenic drugs of any kind sold in the United States. Indeed, Plaintiff made this one of the central points of her jury arguments. (Tr. 1628, 1658, 1724, 1727, 1728, 1730, 1731, 1734, 1756, 1762).

But Minnesota law is clear that a punitive damages award can be based *only* on the underlying theory of liability for the plaintiff's compensatory claim. *See Hodder*, 426 N.W.2d at 836 (holding that it was impermissible for a jury to award punitive damages for a manufacturer's failure to recall its product where the failure to recall was not an underlying basis for the manufacturer's liability). And Plaintiff's warnings expert, Dr. Blume, never testified that Abbott should have warned about how Depakote's risk of birth defects compared to that of every other drug sold in the United States. Because Plaintiff's underlying failure to warn claim was not based on a theory that Abbott should have warned about how Depakote's risks compared to those of every other drug sold in

the United States, as a matter of Minnesota law Abbott could not be held liable for punitive damages for failing to provide such a warning.

Moreover, Minnesota law is also clear that for a defendant's actions to be a basis for a punitive damages award, those actions must have been a proximate cause of the plaintiff's injuries. *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"); *Anderson v. Amundson*, 354 N.W.2d 895, 897 (Minn. App. 1984) (a plaintiff "seeking to recover punitive damages . . . is required to prove that the [defendant's conduct] was the proximate cause of the plaintiff's injuries").[21] Plaintiff presented no evidence that Ms. Vititoe's prescribing physician, Dr. Jacoby, based his AED prescribing decisions on how an AED's risks compared to drugs *other than AEDs*. As a result, Abbott's purported

[21] Minnesota is not alone in this respect. *See, e.g.*, *Lamb v. Mendoza*, 478 F. App'x 854, 857 (5th Cir. 2012) (stating that plaintiff was not entitled to a jury instruction on punitive damages because defendants' alleged "reckless disregard" for plaintiff's health was not a "proximate cause" of plaintiff's injury); *Ventas, Inc. v. HCP, Inc.*, 647 F.3d 291, 319 (6th Cir. 2011) (stating the "law requires a plaintiff seeking punitive damages to prove that the relevant actions of the defendant were the proximate cause of the resulting injury to the plaintiff"); *Stogsdill v. Healthmark Partners, L.L.C.*, 377 F.3d 827, 832 (8th Cir. 2004) (finding error where the jury may have "base[d] its punitive damages award on evidence unrelated to the treatment [plaintiff] received").

failure to provide a comparison of Depakote's risks to the risks of every other drug sold in the United States was not a proximate cause of Plaintiff's injury and therefore cannot support a punitive damages award under Minnesota law.

As another example, Plaintiff criticized Abbott for obtaining the FDA's approval of Depakote for the treatment of two medical conditions other than epilepsy—manic episodes in bipolar disorder and migraine headaches. (*See*, *e.g.*, Tr. 1632-33, 1727, 1777, 1780). According to Plaintiff, Abbott should not have sought those expanded FDA approvals because a substantial portion of the patients with those conditions are women of childbearing age. But Ms. Vititoe took Depakote for the treatment of epilepsy, not for manic episodes or migraine headaches. So the approval of Depakote for conditions other than epilepsy was not a proximate cause of Plaintiff's injury and therefore cannot support a punitive damages award under Minnesota law.

Similarly, Plaintiff criticized Abbott for marketing Depakote as a "first-line" choice for seizure control. (Tr. 1634-35, 1780). But 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. Indeed, Dr. Jacoby testified that every patient reacts differently to AEDs, so you cannot employ a "one size fits all" strategy when prescribing AEDs. (Tr. 1177). (*See also* Tr. 1180-81 (Dr. Jacoby testifying: "Every medicine is different and every person is different. So you have got to mix the medicine with the person, and that's where the art in medicine comes in."). In short, Abbott's marketing was not a proximate cause of Plaintiff's injury and therefore cannot support a punitive damages award under Minnesota law.

E. The Court of Appeals Misapplied Minnesota's Punitive Damages Statute, Which Further Demonstrates Why This Case Does Not Belong in Missouri.

In addition to ignoring *In re Levaquin*, the Court of Appeals also misapplied the applicable Minnesota statute governing punitive damages by incorrectly conflating the "deliberate disregard" standard required to establish *liability* with the factors to be considered in determining the *amount* of punitive damages.

An award of punitive damages under Minnesota law requires a two-step process. As a threshold matter, clear and convincing evidence must establish that the defendant acted with deliberate disregard for the safety of others. Minn. Stat. Ann. § 549.20.1. If the "deliberate disregard" standard is not met by clear and convincing evidence, then punitive damages are not permitted, and the inquiry ends. If—and only if—the clear and convincing evidence establishes deliberate disregard, then the *amount* of the award is to be measured by, *inter alia*, several factors enumerated in the statute. *See* Minn. Stat. Ann. § 549.20.3. Thus, deliberate disregard is a threshold showing that must be established *before* the factors set forth in subdivision 3 are considered to determine an amount. *See, e.g., Hooser v. Anderson*, No. A14-1055, 2015 WL 1959898, at *6 (Minn. App. Apr. 25, 2016). The Court of Appeals Opinion's extensive discussion of the factors in assessing *liability* for punitive damages misapplied Minnesota law.

No court has the experience or expertise to routinely and correctly apply the law of all fifty states. As demonstrated above, the Circuit Court and Court of Appeals overlooked important features of Minnesota law, both from the relevant statute and from

the applicable case law that should be afforded great deference. The risk of additional mistakes will only increase as the burden from the claims of out-of-state plaintiffs grows.

CONCLUSION

Because the Circuit Court erred in denying Abbott's venue and severance motions, this Court should vacate the judgment and remand the case to the Circuit Court to either transfer or dismiss it. If this Court rejects Abbott's venue and severance arguments, the Court should vacate the judgment and remand the case to the Circuit Court with a mandate to enter judgment in favor of Abbott on Plaintiff's failure-to-warn claim. In the alternative, the Court should vacate the punitive damages award.

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 24,845 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 February 28, 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