Case No. SC96151

IN THE
SUPREME COURT OF MISSOURI

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

RESPONDENTS' SUBSTITUTE BRIEF

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INTRODUCTION

Appellant Abbott Laboratories, Inc. ("Abbott") appeals following a jury verdict and judgment favoring Respondent Maddison Schmidt, who was born with catastrophic birth defects after *in utero* exposure to Depakote, an antiepileptic drug manufactured and marketed by Abbott. Hoping to relitigate the case in this Court, Abbott's Statement of Facts fails its duty to provide the Court with the facts that support the verdict. This Statement of Facts is unfortunately necessary to provide the Court with what Abbott failed to provide – the facts the jury found that control appellate review.

STATEMENT OF FACTS

A. Background

Respondent Maddison Schmidt was born on April 24, 2003. She suffers from spina bifida, microcephaly, brain malformations and a congenital eye defect caused by *in utero* exposure to Depakote, an antiepileptic drug marketed by Abbott and prescribed to her mother for her epileptic seizures. Tr.754-55, 782-87, 792, 807. Maddison is paralyzed, lacks bowel and bladder control, is severely cognitively impaired and will require extensive medical and other care for life. Tr.688-89, 691, 712-15, 717-23, 735-38.

Abbott has marketed various forms of Depakote (the brand name for valproic acid, or "VPA") since 1978. Tr.497-98. Abbott has a continuing duty to provide adequate warnings to doctors on its Depakote drug label, annually published in the Physicians' Desk Reference (PDR). Tr.993-97, 1012-13, 1021-24. Abbott is primarily responsible for the safety of Depakote and has a duty to be the expert on its safety, including ensuring that the

label's warnings and instructions for use remain adequate and up-to-date.[1] Tr.975-80, 995, 1004-13.

Depakote was approved initially to treat certain types of epileptic seizures, and later for manic episodes associated with bipolar disorder (1995) and migraine headaches (1996). By the early 2000s, Depakote was Abbott's biggest selling product.[2] At the time of Maddison's conception in 2002, one of Abbott's top corporate objectives was for Depakote to become the company's first drug to exceed $1 billion in annual sales. SLF2609 at 161.

B. Abbott Has Known Depakote Causes Severe Birth Defects For Decades.

Depakote causes an array of serious birth defects, including spina bifida, craniofacial, heart, skeletal and urogenital defects, as well as cognitive impairment. Tr.754-55, 784, 796.

Antiepileptic drugs as a class (which includes Depakote and other competing drugs available to treat epilepsy) are sometimes referred to as "AEDs." AEDs in general have long been understood to pose some risk of birth defects. However, to a developing fetus, Depakote is unquestionably the most dangerous AED and is one of the most teratogenic

[1] Supplemental Legal File (hereinafter "SLF") 2497 at 17-18; SLF2502 at 129-30; SLF2551 at 31; 2557 at 146; SLF2606 at 49-50; SLF2607 at 50-51.

[2] SLF2609 at 161. *See also* SLF2968, SLF2976; SLF2523 at 48; SLF2524 at 48, 51; SLF2525 at 66; SLF2526 at 66-67; SLF2585 at160; SLF2586 at 160-61.

drugs ever sold on the market.[3] Tr.492, 504-06, 506-09, 513-14, 520-21, 527-28. Nonetheless, Abbott falsely labeled Depakote as a drug with a similar degree of birth defect risk as other AEDs, and despite its dangers marketed the drug as a "first-line" or "first-choice" treatment for women of childbearing years.[4]

Abbott has been aware of Depakote's propensity to cause birth defects since the 1980s. In 1982, a French researcher discovered a significant increase in spina bifida in children exposed to Depakote *in utero*. Tr.507-10. This resulted in a revision to the Depakote label to reflect the reported association of a 1-2 percent risk of spina bifida. Tr.536, 559-62, 568-69. At the time, Abbott consultants offered to design studies to further investigate the dangers of the drug during pregnancy. Abbott declined and performed no studies or investigation of the degree of the drug's birth defect risks as the years progressed.[5] Tr.545-47, 621.

Information regarding Depakote's danger mounted. As a result, Abbott was acutely aware that Depakote had an increased overall risk of birth defects versus its competitors

[3] SLF2547 at 786, 792-93; SLF2548 at 793; SLF2549 at 850.

[4] SLF2529 at 159, 161; SLF2530 at 161; SLF2531 at 174; SLF2532 at 174-175. *See also* SLF3102, SLF3151; SLF2601 at 244; SLF2574 at 72-75.

[5] SLF2529 at 111; SLF2538 at 88; SLF2560 at 538-39.

and was significantly more dangerous for use in women of childbearing age.[6] Tr.1021-24. Before the time of Maddison's conception, Abbott knew of many studies concluding that (1) Depakote posed a higher risk of birth defects than its competitor AEDs,[7] (2) the overall risk of birth defects was 10 percent or even greater,[8] (3) the risk of spina bifida was significantly higher than the 1-2 percent stated in the label,[9] and (4) the risk of spina bifida

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[6] SLF2632; SLF3176-79; SLF2612 at 207, 212, 213; SLF2549 at 850; SLF2557 at 242; SLF2565 at 107.

[7] SLF2611 at 201-04; SLF2612 at 207, 212-13; SLF2557 at 242; SLF2564 at 88; SLF2565 at 107; SLF2632; SLF3243; SLF2549 at 850; Tr. 1500, 1505-06.

[8]SLF2515 at 278-79; SLF2517 at 288-90; SLF2518 at 290, 314; SLF2519 at 314, 319, 327, 331; SLF2520 at 331-33; SLF2557 at 242, 303-05; SLF2558 at 306-07; SLF2591 at 229-30.

[9]SLF2564 at 106; SLF2565 at 106-07 ("And so Dr. Samrin found that you were off, that [the risk of spina bifida] was actually almost twice what was in your label, correct? That's the results of this meta-analysis, yes."); *see also* Tr. 511-12, 516-17; SLF2550 at 963-64. Abbott's brief says that one of Respondent's experts testified that the 1-2% risk of spina bifida was "entirely accurate." Sub.App.Br.29. In fact, Dr. Edward Lammer, Respondent's specific causation expert, testified among other things that the absolute risk for major birth defects with Depakote is ten to eleven percent, that studies have demonstrated the risk of spina bifida to be as high as two to five percent (one in twenty

amounted to a twentyfold increased risk compared to the background rate in the general population.[10]

Before Maddison's conception, Abbott was also specifically advised that Depakote should not be prescribed to women of childbearing years unless all other alternatives had been tried and failed, and Abbott was aware of scientific literature concluding the same.[11] Despite this substantial actual knowledge, Abbott's label falsely stated that sufficient data to determine the incidence of birth defects was "not available." Tr.1026-32, 1219-22.

C. Abbott's 2002 Depakote Label was False and Misleading.

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babies), that the risk of spina bifida with Depakote has been assessed to be twenty, thirty up to even eighty times greater than the rate in the background population, and that Depakote is "more toxic than any of the other anticonvulsants and causes a higher percentage of babies to be adversely affected than any of the other anticonvulsants." Tr. 896-900; *see also* Tr. 1494, 1497, 1559.

[10] Tr. 518, 521, 566, 589, 794, 897-98, 915, 1021-24, 1026-28, 1031-32, 1497, 1493-94, 1502-05, 1511-12.

[11] SLF3177-80; SLF2578 at 100; SLF2579 at 100-03; SLF2580 at 110-11; SLF2590 at 201-02; SLF2591 at 202; SLF2593 at 236; SLF2594 at 236; SLF2564 at 89; SLF2565 at 109; SLF2566 at 109-10.

The 2002 Depakote label contained false and misleading statements such that prescribing doctors like Dr. Robert Jacoby, the prescribing physician in this case, were not adequately warned.

For example, while Abbott's label did convey the reported 1-2 percent risk of spina bifida, the label contained outdated information comparing Depakote to other drugs in its class. Indeed, for over 20 years Abbott represented that Depakote's teratogenicity was the same or even less than other drugs:

> 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.[12]

This claim, first made in 1980, remained static and unchanged through Maddison's 2002 conception. As noted above, Abbott knew by at least 2002 that Depakote was the most dangerous drug in its class.

[12] SLF3248 (emphasis added), SLF3252; *see also* Tr.1027-28, 1217-19, 1221-22.

Likewise, contrary to what Abbott knew to be true, from the early 1990s through the time of Maddison's 2002 conception, Abbott included false statements about the risk of birth defects:

> OTHER CONGENITAL ANOMALIES (EG, CRANIOFACIAL DEFECTS, CARDIOVASCULAR MALFORMATIONS AND ANOMALIES INVOLVING VARIOUS BODY SYSTEMS), COMPATIBLE AND INCOMPATIBLE WITH LIFE, HAVE BEEN REPORTED. SUFFICIENT DATA TO DETERMINE THE INCIDENCE OF THESE CONGENITAL ANOMALIES IS NOT AVAILABLE.

SLF3252 (emphasis added). The highlighted statement was patently false. (Abbott's brief omits this statement when quoting the above portion of the label. Sub.App.Br.29.) Abbott's label failed to mention studies consistently showing the overall danger of birth defects with Depakote to be ten percent or much greater and that Depakote had been associated with a significantly higher risk of teratogenicity than all other AEDs. *See, e.g.*, Tr.1021-24, 1026-32, 1119-20.

Further, from 1980 through Maddison's 2002 conception, Abbott went so far as to deny that any increase in congenital anomalies was attributable to exposure to Depakote at all:

> THE HIGHER INCIDENCE OF CONGENITAL ANOMALIES IN ANTIEPILEPTIC DRUG-TREATED WOMEN WITH SEIZURE DISORDERS CANNOT BE REGARDED AS A CAUSE AND EFFECT

RELATIONSHIP. THERE ARE INTRINSIC METHODOLOGIC PROBLEMS IN OBTAINING ADEQUATE DATA ON DRUG TERATOGENICITY IN HUMANS; GENETIC FACTORS OR THE EPILEPTIC CONDITION ITSELF, MAY BE MORE IMPORTANT THAN DRUG THERAPY IN CONTRIBUTING TO CONGENITAL ANOMALIES.

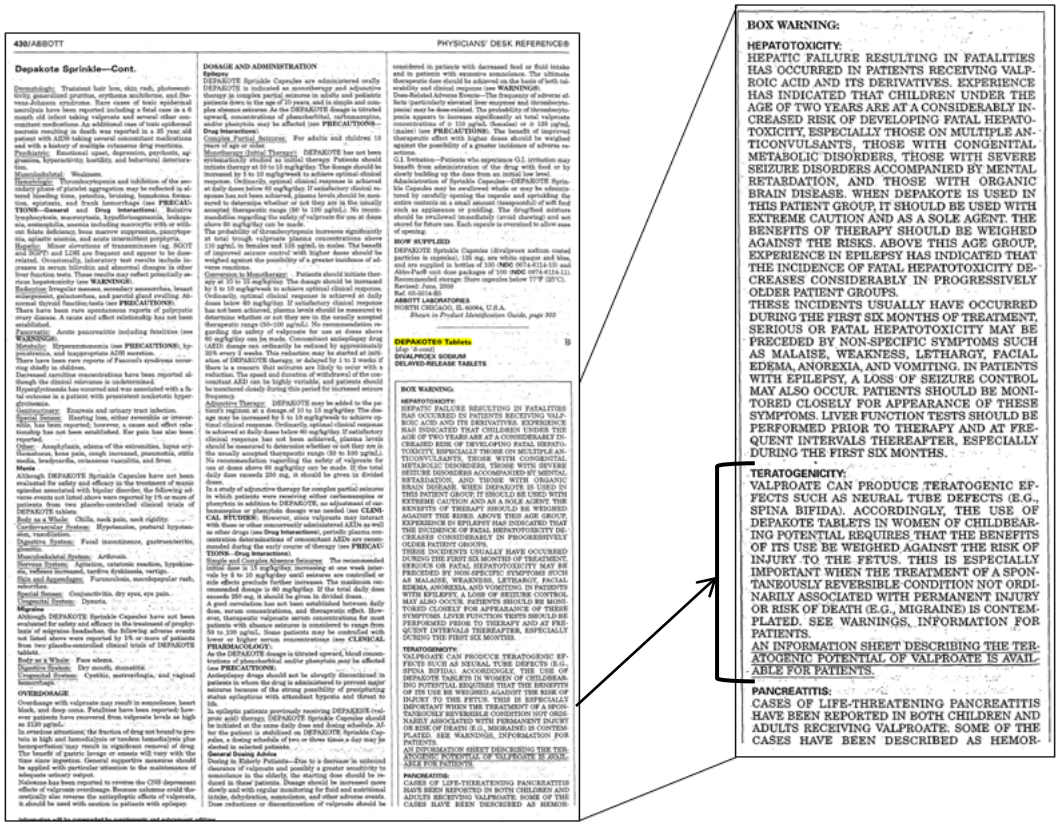
SLF3252 (emphasis added).

Critically, the label also failed to warn that Depakote should not be prescribed to women of childbearing years unless all other alternatives had been tried and failed. *See, e.g.,* Tr.1021-24, 1030-32, 1522.

Abbott touts the "black box" warning in the Depakote label as if its mere existence absolves it from any requirement to provide an adequate warning or to update the information given to physicians. Contrary to Abbott's depiction of the "black box" or "box" warning in its brief,[13] Abbott's box warning was essentially a statement acknowledging that the drug "can produce teratogenic effects" as well as two other possible side effects of Depakote use:[14]

[13] This type of warning is referred to colloquially as a "black box" warning, but is actually titled "box warning" in medication labels like the 2002 Depakote label.

[14] SLF3252. The image above is the actual excerpted page upon which the Depakote Tablets label is found in the 2002 PDR.



Abbott's "black box" warning was added to the Depakote label in 1996 not as a means to provide additional warnings or information but because Abbott sought to expand its market to sell this antiepileptic drug for migraine headaches.[15] Abbott representatives admitted that this action did not result in the addition of any new substantive information or warnings.[16]

[15] Tr.1037-41, 1515-17, 1521. *See also* SLF2614 at 362; SLF2615 at 362-63.

[16] SLF2614 at 362; SLF2615 at 362-63 (it "was not new – new information"). In addition, Abbott's expert witness admitted that the box's admonition to weigh the benefits of the drug against the risks is something that would apply to any drug on the market.

In addition, compared to the warnings information already in the Depakote label, the box warning did not indicate any additional level of teratogenic risk for Depakote compared to other AEDs, did not convey a host of information known to Abbott about the degree of teratogenic risk of the drug, and did not warn or instruct physicians to avoid use of Depakote in women of childbearing years unless alternative treatment options had failed. Tr.1209-12, 1215-16. Nor did Abbott update the label as important information about the drug's dangers came to light after 1996. Tr. 1039-41, 1047. And, as the Missouri Court of Appeals, Eastern District, noted, Abbott was "specifically advised that Depakote should not be prescribed to women of childbearing years *unless all other alternatives had been tried and* failed and [Abbott] was aware of scientific literature concluding the same." Slip.Op.13. That information was not included by Abbott in the warning provided to doctors like Dr. Jacoby in this case. Tr. 1039-41, 1047.

D. Abbott Intentionally Withheld Safety Information.

Abbott conducted zero studies or independent research efforts to evaluate Depakote's safety in pregnancy, but expended great effort and $50-100 million per year marketing the drug. SLF2522 at 34. Depakote was Abbott's "cash cow" and Abbott's express plans for the early 2000s were to "squeeze every dollar and every prescription we

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Tr.1510-11, 1515-17. He also testified that the statement in the box warning, that Depakote "can produce teratogenic effects," would have been true of any AED on the market at the time. Tr. 1510-11, 1516.

can out of the market"[17] despite knowing that "safety in women" was one of the factors that "drives the AED market." SLF2583 at 138-39.

Testimony from Abbott employees as well as documents[18] revealed that safety issues including birth defects led to Depakote being known internally as a "dirty drug." SLF2524 at 58. Nonetheless, Abbott's goals for the year of Maddison's conception were: "expand the use of Depakote in women" and to grow market share "or we will die."[19]

Despite knowledge of Depakote's true risk of birth defects, information relating to the risk of birth defects was regarded internally at Abbott as an "obstacle" to sales, placing Depakote "under increasing attack," and was "damaging to Depakote."[20] Not only did Abbott fail to provide accurate information and correct misleading information provided to physicians, its stated strategy was precisely the opposite: to "expand the use of Depakote

[17] SLF2526 at 91-92; SLF2985, SLF3077.

[18] The Court of Appeals opinion recites some of this evidence as well. *See* Slip Op. at 14-17, 19-20.

[19] SLF2529 at 160-61; SLF2530 at 161, 163, 166; SLF2531 at 166-67; SLF3100.

[20] SLF2600 at 210; SLF2611 at 201-04; SLF2612 at 204, 207; SLF2530 at 166; SLF2531 at 166-68; SLF2571 at 113-14; SLF2572 at 116; SLF2586 at 166-67; SLF2587 at 167-69; SLF2632.

in women" and "maintain Depakote's position as a first line agent for women with epilepsy."[21]

E. Dr. Robert Jacoby's Prescription Decision And Maddison Schmidt's *In Utero* Depakote Exposure.

Dr. Robert Jacoby is the neurologist who treated Maddison's mother, Tiffany Vititoe, for epileptic seizures. Tr.1166-69. Dr. Jacoby testified that there were other available options to treat Maddison's mother's epileptic condition. Tr.1209-10, 1224-25, 1320. In assessing whether to prescribe Depakote to a woman of childbearing age, Dr. Jacoby weighed the benefits against the risks that were disclosed, specifically the total risks of the drug to a fetus. Tr.1182-84, 1223.

Dr. Jacoby reviewed and relied upon Abbott's 2002 Depakote label. Tr.1209-12, 1215-22. Dr. Jacoby appropriately viewed the black box as the "executive summary" of the warning that directs prescribing physicians to the details in the warning section of the label. Tr.1213. Dr. Jacoby testified about his understanding of the fetal risks of the drug, how he counseled patients, and that Abbott's warning label told physicians that Depakote had a similar birth defect risk as the other available antiepileptic medications.[22]

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[21] SLF2529 at 159, 161; SLF2530 at 161; SLF2532 at 174-75; SLF2533 at 175; SLF3102; SLF3151; SLF2601 at 244, 248-49; SLF2602 at 248-49; SLF2574 at 72-73, 75.

[22] Tr.1183-84, 1192-93, 1198-1200, 1209-10; 1215-22. Abbott's expert neurologist said the same. Tr.1453-56, 1515-17, 1521-22.

Dr. Jacoby testified that when treating women of childbearing age in 2002, he was concerned about the total risk of birth defects associated with a drug. Tr. 1183. The 2002 Depakote label indicated to him that there was not enough data to "make any comments" about the overall incidence of congenital malformations. Tr. 1220. He further testified that the label indicates that there is not a cause and effect relationship between *in utero* Depakote exposure and birth defects. Tr. 1221.

He testified that the Depakote label did not warn of the drug's total risk of birth defects (stating instead that such information was unavailable), did not convey that it was more dangerous than other AEDs (indeed, the opposite), and did not warn that Depakote should not be used in women of childbearing years unless all other treatments had been tried and failed. Tr.1215-22, 1225. Had Abbott made him aware of such information, he would not have prescribed Depakote to Maddison's mother. Tr.1185, 1209, 1221-23, 1232, 1313-14, 1320. Dr. Jacoby further testified that there were other viable treatment options for Maddison's mother, but there was no cause to consider those because the thought was that all AEDs carried a similar risk – a perception supported by the statements in the 2002 Depakote label. Tr. 1225-32.

F. Maddison's Permanent Damages

Maddison has spina bifida and other physical and cognitive injuries associated with spina bifida. Tr.754-55, 779-80, 782-87. Abbott ignores that she also was diagnosed with multiple birth defects caused by Depakote independent of her spina bifida, including microcephaly, ocular coloboma (a congenital eye defect), brain malformations and cognitive impairment. Tr.643, 754-55, 779-80, 782-87. She is mentally handicapped and

has an IQ between 55 and 61 (bottom 1%). Tr.649-51, 679, 775-76, 779-80, 785-91. She is paralyzed below the waist and confined to a wheelchair. Tr.646-49, 661-63. She has a neurogenic bowel and bladder (loss of nerve function and sensation of the bladder and bowel), which requires that she be catheterized several times a day, and also that she have her stool manually removed at times. Tr.664-67. She has had several surgeries, including the placement of a shunt in her skull, shunt revisions and spinal surgeries. Tr.647, 651, 654, 657-58, 671-76, 779-80.

Maddison is being raised by her grandparents, who are her legal guardians and who brought this case on her behalf. Her grandfather was present throughout the trial and testified. Tr.1121-62. Because of her permanent physical and cognitive impairment, Maddison will never be able to live independently, support herself financially, or live a remotely normal life. Tr.662-64, 679-86, 688-96, 1141-48.

The jury learned of life care plan options for Maddison that ranged from $10,720,347 to $19,629,678 in adjusted future costs, and was presented with ranges estimating Maddison's lost wage earning capacity. Tr.931, 940-41. Abbott did not contest this evidence.

G. Relevant Procedural Background

Maddison's claim was joined with similar claims brought by 24 others in an action filed on May 21, 2012. LF35. Maddison's case was selected as the first trial case. LF35.

Abbott raised its venue and joinder challenges on numerous occasions before trial. They were rejected by both state and federal courts:

- **U.S. District Court for the Eastern District of Missouri**: Abbott removed the case arguing misjoinder. In granting the plaintiffs' motion to remand, the federal court found that "Plaintiffs' claims are sufficiently related to support joinder in this case." SLF2188, SLF2191.
- **Trial Court**: Abbott's venue and forum *non conveniens* motions were denied, including one on the eve of trial. The trial court found the claims were properly joined, venue was proper, and that the forum was not inconvenient. SLF49-52; SLF79; SLF2178-87; SLF2233.
- **This Court and the Missouri Court of Appeals, Eastern District**: Abbott sought writs in the Missouri Court of Appeals, Eastern District, and this Court related to its venue and joinder challenges before this case was tried. The same arguments were made then and now. Both this Court and the Missouri Court of Appeals denied the writs. SLF2193; SLF2195.

The trial was bifurcated and the jury returned two verdicts: (1) $15 million in compensatory damages and (2) $23 million in punitive damages. SLF2231-32. This yields a ratio of compensatory to punitive damages that is less than 2 to 1 (1.53-1).

Abbott challenged the jury's verdicts in extensive post-trial motions. The trial court denied the motions and "specifically reviewed the jury's $23 million punitive damages award against Defendant" in light of the factors set forth by Minnesota law.[23] LF3523.

[23]There is no dispute that Minnesota substantive law governs this case.

The trial court held that "the jury's award of punitive damages was supported by the evidence adduced at trial, in accordance with the statutory factors, and not excessive." LF3524. The trial court entered judgment accordingly. LF3525.

Abbott appealed the judgment to the Missouri Court of Appeals, Eastern District (hereinafter "the Court of Appeals"). On November 8, 2016, the Court of Appeals issued its opinion affirming the trial court's judgment. The Court of Appeals held that Maddison Schmidt's claim was properly joined with other plaintiffs, venue was proper in the City of St. Louis, and the trial court did not abuse its discretion in denying Abbott's motions for severance. Slip.Op.9. The Court of Appeals also held that the jury's liability, actual damages and punitive damages verdicts were supported by the evidence introduced at trial. *Id.* at *19-33. The Court of Appeals agreed with the trial court's holding that the jury's award of punitive damages was "in accordance" with the statutory factors and "not excessive." *Id.* at *33.

Abbott filed a motion for rehearing or transfer. The Court of Appeals transferred this case to this Court on January 5, 2017.

ARGUMENT

I.

STANDARD OF REVIEW

The meaning of Missouri statutes present questions of law that are reviewed *de novo*. *Joshi v. Ries*, 330 S.W.3d 512, 514-15 (Mo. App. E.D. 2010). In addition, an appellate court should not reverse any trial court judgment unless it finds that the trial court's error materially affected the merits of the action. Rule 84.13(b) (A-29); *Heintz v. Woodson*, 758 S.W.2d 452, 454 (Mo. banc 1988).

A. Introduction and Summary of Point I Argument

Point I asserts that venue over this case was proper only in St. Louis County. The plain language of the venue statute defeats this argument. Abbott attempts to shift the focus of this appeal from the statute to a so-called "litigation crisis." The proper application of the law is all that matters. The consequences of the law are issues for the executive and legislative branches of government.

No doubt Abbott wishes it had challenged personal jurisdiction in this case. If the litigation crisis Abbott bemoans was actually fomented by this case, Abbott could have taken steps to assert a jurisdictional claim to test the propriety of Missouri courts hearing this case. It did not, and that issue is now waived. That failure alone unmasks the purpose of Abbott's venue arguments.

As Point II shows, joinder in this case was proper under the controlling precedent. Unlike any case cited by Abbott, this action involves a single defendant,

in which several plaintiffs joined in a single action averring common liability of Abbott to all plaintiffs.

The controlling venue statutes, §508.010.4 & .5 (A-2), are silent on the interplay of joinder and venue.[24] Abbott's entire statutory argument turns on this Court presuming that

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[24] The legislature has addressed that silence (which shows there was silence to address) in HCSHB 460, which has passed the House and which amends §507.040 (A-1) to read:

> 3. In addition to the requirements of subsection 1 of this section, in any civil action in which there is a count alleging a tort, two or more plaintiffs may be joined in a single action only if each plaintiff could have separately filed an action in that venue, independent of the claims of any other plaintiff. Any plaintiff that cannot establish proper venue independent of the claims of any other plaintiff shall be deemed misjoined. If the plaintiff was first injured outside of the state of Missouri, two or more defendants may be joined in a single action if the plaintiff can establish proper venue against each defendant individually, and if proper venue cannot be established against any such defendant individually, that defendant shall be deemed misjoined.

That bill also amends Section 508.010 as follows:

> Section 15. Notwithstanding any other provision of law, in any civil action in which there is a count alleging a tort, each plaintiff shall independently establish proper venue. It is not sufficient that venue is proper for any other plaintiff joined in the

silence creates an ambiguity in the venue statutes. Silence does not create an ambiguity. *Kerperien v. Lumberman's Mut. Cas. Co.*, 100 S.W.3d 778, 781 (Mo. banc 2003). But "[i]t is readily apparent that [the venue statutes]… do not in express terms cover all possible situations likely to arise." *State ex rel. Rothermich v. Gallagher*, 816 S.W.2d 194, 200 (Mo. banc 1991). Where no venue is prescribed, "we are left to the conclusion that the legislature did not intend to prescribe a particular venue under the present set of circumstances." *State ex rel. Neville v. Grate*, 443 S.W.3d 688, 695 (Mo. App. W.D. 2014).

"The purpose of the venue statutes is to provide a convenient, logical and orderly forum for litigation." *Rothermich*, 816 S.W.2d at 196. The convenience protected by venue statutes is the defendant's convenience since plaintiffs choose the place the action is filed. The statutory designation of a site where venue is proper "presupposes [a] legislative determination that it cannot be overly inconvenient for a defendant to appear in that location." *Willman v. McMillen*, 779 S.W.2d 583, 586 (Mo. banc 1989). Where the statutorily assigned venue is proper as to a defendant and some plaintiffs (a legal conclusion that Abbott admits exists here), venue is necessarily "a convenient, logical and

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civil action. Venue cannot be established by joinder or intervention. The claims of any plaintiff who cannot independently establish venue shall be deemed misjoined, and the claims of any such plaintiff shall be severed and transferred to a county in which venue exists. If there is no county in Missouri in which venue exists, such claims shall be dismissed without prejudice.

orderly forum for litigation" for parties properly joined in a proper venue. *See State ex rel. Wyeth v. Grady*, 262 S.W.3d 216 (Mo. banc 2008) (denying *forum non conveniens* transfer where only 21 of the 186 plaintiffs were Missouri residents because the presence of the Missouri plaintiffs made the venue convenient). Yet, Abbott argues that it is inconvenient for it to try this claim in the City of St. Louis, even though it must admit that the statute makes it convenient for Abbott to defend virtually identical claims against other plaintiffs in the same case there.

Even if venue, which is no longer jurisdictional under Missouri law, is found to be improper, Abbott cannot show prejudice resulted from a trial in the City of St. Louis. Abbott's argument is that improper venue is presumed prejudicial; but this Court has never faced this issue since the legislature made venue merely procedural and not jurisdictional. *State ex rel. DePaul Health Ctr. v. Mummert*, 870 S.W.2d 820, 821 (Mo. banc 1994) (overruling "a long line of Missouri case law … in which Missouri courts held that … a trial court without venue over an action could not obtain personal jurisdiction over a defendant").

Moreover, Rule 84.13(b) permits reversal of a judgment only if the Court finds that claimed error materially affected the merits of the case. Trying this case ten miles away from Abbott's preferred venue in the same judicial system with the same substantive and procedural safeguards and appeals to the same court of appeals cannot be materially prejudicial unless this Court is prepared to say that trials in the City of St. Louis courts are materially prejudicial to defendants (at least those who happen to lose) as a matter of law.

B. Venue Was Proper in the City of St. Louis Under a Straightforward Application of Section 508.010 R.S.Mo.

The language of the statute and applicable precedent shows that venue was proper in the City of St. Louis.

1. Sections 508.010.4 & .5 are silent as to venue when multiple plaintiffs are properly joined.

Section 508.010 provides:

> 4. Notwithstanding any other provision of law, ***in all actions*** in which there is any count alleging a tort and in which ***the plaintiff was first injured in the state of Missouri***, venue shall be in the county where ***the plaintiff was first injured*** by the wrongful acts or negligent conduct alleged in the action.
>
> 5. Notwithstanding any other provision of law, in all actions in which there is any count alleging a tort and in which the plaintiff was first injured outside the state of Missouri, venue shall be determined as follows:
>
> > (1) If the defendant is a corporation, then venue shall be in any county where a defendant corporation's registered agent is located or, if the plaintiff's principal place of residence was in the state of Missouri on the date the plaintiff was first injured, then venue may be in the county of the plaintiff's principal place of residence on the date the plaintiff was first injured;

§508.010, RSMo. (emphasis added).

"It is readily apparent that [the venue statutes]… do not in express terms cover all possible situations likely to arise." *Rothermich*, 816 S.W.2d at 200. Where no venue is prescribed, "we are left to the conclusion that the legislature did not intend to prescribe a particular venue under the present set of circumstances." *Grate*, 443 S.W.3d at 695.

Simply put, Abbott's assertion that the statute requires a plaintiff-by-plaintiff assessment of venue finds no textual support in the statute. Indeed, the statute's application turns on the existence of an "action." "An action is a legal demand of one's rights in a court of justice, or a legal proceeding in a court of justice to enforce a right or to redress a wrong." 1A C.J.S. Actions § 1 (A-59). Rule 42.01 (A-18) provides: "There shall be one form of action to be known as 'civil action.'" A civil action is initiated by a petition. Rule 55.01 (A-27). The venue statutes demand that the court look at the action. Consistent with this understanding, this Court has concluded that venue is determined from the face of the petition, that is, from the face of the document that commences the action. *State ex rel. Doe Run Res. Corp. v. Neill*, 128 S.W.3d 502, 504 (Mo. banc 2004).

Here, the "action" is one by multiple plaintiffs against a single defendant. It is fundamental that the language of the venue statute requires *first* an assessment of the action and *then* a determination of application of the venue statute. If the action is one that the rules permit (properly joined plaintiffs), "plaintiffs may file suit in any statutorily permissible venue." *Id.* Only where joinder is not pretensive – a judgment that requires an initial assessment of the "action" – will a court question the plaintiffs' venue choice. *Id.* On its face, the petition here pleads facts that make venue proper in this case in the City of St. Louis.

2. Section 508.010 permits properly joined plaintiffs to file in either of two statutorily-prescribed venues where both in-state and out-of-state plaintiffs sue defendants in a county where venue is proper as to all defendants.

By its plain terms, Section 508.010.4 applies to this action. Under the statute, two venues would have been proper, the City of St. Louis and St. Louis County. This is because some plaintiffs in the action fall under Section 508.010.4 (first injured by Abbott in the City of St. Louis) and others fall under Section 508.010.5 (injured by Abbott outside of Missouri).

The statute is silent when both scenarios occur in a single case. The trial court found, and Point II shows, that the joinder here among plaintiffs was proper.

Abbott looks to a law review article by Professor David Achtenberg for support. Yet, even Professor Achtenberg acknowledges that "[o]n its face, the [Tort Reform] act [of 2005, which amended the venue statute] *does not seem to indicate how these rules apply* in actions in which some plaintiffs are first injured within the state and some outside it." David Jacks Achtenberg, *Venue in Missouri After Tort Reform*, 75 UMKC L.REV. 593, 621 (2007). ***This confession alone resolves the issue***. "Does not seem to indicate how these rules apply" is long-hand for silence.

Resorting to canons of construction is *verboten* absent ambiguity. Indeed, this Court has addressed silent statutes, concluding that facial statutory silence does not equate to actual ambiguity and that where a statute provides no guidance, it provides no guidance:

> Rules of construction are not to be used if the statute contains no ambiguity.
>
> In this case, the legislature made no specific provision for a post-trial settlement. Rather, the statute addresses only two situations: where an amount is recovered with a finding of comparative fault, and where an amount is recovered without a finding of comparative fault. The statute does not contain an ambiguity….

Kerperien, 100 S.W.3d at 781.

Legislative intent is determined only by the words used where the statute is not ambiguous. It is not absurd at all for the legislature to have intended the normal joinder rules to apply in an action. Judicial efficiency is a purpose that joinder serves; the legislature that passed the venue statute did not find judicial efficiency absurd.

Abbott asks the Court to read additional words or requirements into the venue statutes that are not spelled out in those statutes. To support this argument, Abbott refers the Court to Professor Achtenberg's article in which he suggests that subsections .4 and .5 could be interpreted as a single, cumulative venue statute, rather than as an independent (or distributive) venue rule. Sub.App.Br.57-58. This cumulative conclusion admits, however, that a word must be added – an "and" between subsection .4 and subsection .5. Adding this word permits Abbott to argue that a court should deem the place of the "first injury" for all plaintiffs to be where the earliest-injured plaintiff was injured. While this might seem like an interesting idea, the statute of course says nothing of the sort.

Indeed, in a footnote that Abbott does not provide to the Court, even the Professor agrees:

> Even reading the sections [.4 and .5] in this way, it would still be possible to construe "plaintiffs" in each section distributively, i.e., to construe the sections as applying only if all the individual injuries to the plaintiffs were suffered either in the state or outside it.

Achtenberg, *op. cit.* at 621 n.186. (2007). But importantly, it is only by adding "and" that Abbott and the Professor can make the argument for a cumulative reading at all.

In fact, the "distributive" reading fits neatly with a conclusion that the legislature's silence was intended and that separate subsections describing two distinct factual predicates for the two independently operable venue provisions fulfill the legislature's plan to assure defendants of a convenient forum as well as efficient conduct of litigation through proper joinder.

The legislature's decision to treat subsections .4 and .5 as two separately operable rules is evidenced by (a) the use of distinctly defined factual scenarios that control the application of each subsection, (b) the fact that the subsections are separately numbered, expressing an intentional and clean bifurcation between subsections .4 and .5, and (c) no "and" or other linguistic linkage between .4 and .5 exists in the statute.

Further, both Abbott and Professor Achtenberg seem unaware of this Court's teaching that there may be two correct venues in a case. *State ex rel. Kansas City S. Ry. Co. v. Nixon*, 282 S.W.3d 363, 367 (Mo. banc 2009). On their faces, subsections .4 and .5 prescribe two independently proper venues in a properly joined action. Indeed, "[v]enue

can be proper in more than one county." *State ex rel. Bank of Am. N.A. v. Kanatzar*, 413 S.W.3d 22, 29 (Mo. App. W.D. 2013). And again, "[t]he purpose of the venue statutes is to provide a convenient, logical and orderly forum for litigation." *Rothermich*, 816 S.W.2d at 196. Where that is so, the plaintiff can choose a venue and a court may not "disturb a plaintiff's choice of proper venue within the State." *State ex rel. Palmer v. Goeke*, 8 S.W.3d 193, 196 (Mo. App. E.D. 1999); *accord State ex rel. Selimanovic v. Dierker*, 246 S.W.3d 931, 932-33 (Mo. banc 2008).

The venue statute does not expressly assign a single venue in circumstances in which both in-state and out-of-state plaintiffs bring a properly joined action. This simply means that the legislature chose to let the venue assignments it did make suffice. Here, because both subsections .4 and .5 establish proper venue over the single defendant, Plaintiffs' choice between the two controls. There is no authority stating that a court or parties should defer to one subsection of the venue statute over the other.

3. Permitting more than one venue in properly joined cases is appropriate.

Permitting two venues in properly joined cases reflects an understanding of the extant statutory and case law as well as the policy choices that are the legislature's alone to make.

First, as noted earlier, venue is no longer jurisdictional. *DePaul Health Ctr.*, 870 S.W.2d at 821.

Second, with jurisdictional concerns removed, venue rules are now properly seen as legislatively chosen, defendant-centric shields against inconvenience and little else, their purpose being to provide "a convenient, logical and orderly forum for litigation."

Rothermich, 816 S.W.2d at 196. The statutory designation of a site where venue is proper "presupposes [a] legislative determination that it cannot be overly inconvenient for a defendant to appear in that location." *Willman*, 779 S.W.2d at 586. Where the statutorily assigned venue is proper as to a defendant and some plaintiffs, something that even Abbott cannot dispute here, the venue is necessarily "a convenient, logical and orderly forum for litigation" properly joined under Rule 52.05 (A-22). The Court can conclude that the legislature presumed that a single defendant sued in the proper venue by multiple plaintiffs in a properly joined action would have no basis for complaining about venue, since the defendant is properly there anyway.

Third, joinder rules further efficiency in court proceedings. "The policy of the law is to try all issues arising out of the same occurrence or series of occurrences together." *Bhagvandoss v. Beiersdorf, Inc.*, 723 S.W.2d 392, 395 (Mo.1987). The legislature is presumed to know that its own stated policy expressed in §507.040 (A-1), copied verbatim in Rule 52.05,[25] applies when a defendant is otherwise in a proper venue. *See Turner v.*

[25] On matters of practice, procedure and pleadings, the statute remains a joint source of law unless there is a conflict between the Supreme Court's Rules and the statute, in which case the Rules prevail. *State ex rel. Union Elec. Co. v. Barnes*, 893 S.W.2d 804, 805 (Mo. banc 1995). Because §507.040 and Rule 52.05(a) are identical, the statute still states the Legislature's policy.

Sch. Dist. of Clayton, 318 S.W.3d 660, 667-68 (Mo. banc 2010) ("It is presumed that the General Assembly legislates with knowledge of existing laws.").

In sum, nothing in §508.010 limits venue to a single county where properly joined plaintiffs sue a *single* corporate defendant in a place where venue is proper as to that defendant for at least some of the plaintiffs.

Not only does a plain reading of §508.010 rebut Abbott's argument, but the cases Abbott cites also fail to provide any support for its interpretation. Indeed, the cases on which Abbott relies make the point that even where there are multiple joined defendants and venue is proper as to only one defendant, "[v]enue exists for all jointly-liable or commonly-liable defendants where it exists for one defendant." *State ex rel. BJC Health Sys. v. Neill*, 121 S.W.3d 528, 530 (Mo. banc 2003) (citing *State ex rel. Bitting v. Adolf*, 704 S.W.2d 671, 673 (Mo. banc 1986) and *State ex rel. City of Springfield v. Barker*, 755 S.W.2d 731, 734 (Mo. App. 1988)). These holdings necessarily conclude that the cause of action that permits joinder is the threshold inquiry for venue purposes and that venue is proper for multiple defendants, even for those for whom venue is not proper, where the case avers common or joint liability by all defendants.

Abbott disapproves of the Court of Appeals' citation to *State ex rel. Allen v. Barker*, 581 S.W.2d 818, 827 (Mo. banc 1979) as to when joinder is considered. Sub.App.Br.47-48. The Court need not even consider this issue. This is because there is no claim in this case – which was present in *Neill* and *Barker* and is absent here – that venue is improper as to a joined defendant. This is a case of first impression precisely because the single defendant here agrees that venue is proper for some cases but contends that it is not proper

for some others. That contention rests on another argument divorced from the text of the venue statutes – that the venue statutes require a plaintiff-by-plaintiff venue assessment even if the action is one involving properly joined plaintiffs.

If this Court wishes to consider the *Neill/Barker* issue, *Neill* suggested that *Barker*'s holding that venue was proper as to all defendants where it was proper as to one of four defendants if they shared common liability for an indivisible injury correctly stated the law, but that *Barker*'s more sweeping comment that "the question of venue is contingent upon proper joinder" went too far. *Neill*, 121 S.W.3d at 530.

Neill's comment, which does not overrule *Barker*, underscores this point: Joinder does determine venue when Rule 52.05 permits joinder of multiple defendants in an action when those defendants are jointly/commonly liable. Again, as the statute at issue here expressly states, it is the "action" itself that controls and requires the first consideration in the venue equation. It necessarily follows as a matter of logic and law that Abbott, the single defendant that plaintiffs aver is liable to all of them for the same reason, is legally and logically indistinguishable for purposes of venue analysis from several defendants facing common/jointly liability. That single defendant, for whom venue is proper as to some plaintiffs in the City of St. Louis, is in the proper venue in the City of St. Louis for all properly joined plaintiffs. The proper joinder of plaintiffs, not defendant**s**, controls the venue question in this case because of the common liability of a single defendant to all plaintiffs. Under the statute and the law, the City of St. Louis is the proper venue for this case.

State ex rel. Turnbough v. Gaertner, 589 S.W.2d 290, 290 (Mo. banc 1979), is the case on which Abbott pins its hopes. *Turnbough* does not require reversal. It is no longer valid law. *State ex rel. Kinsey v. Wilkins*, 394 S.W.3d 446, 453 (Mo. App. E.D. 2013) makes this point when considering the application of the 2005 venue rules to a multiple-defendant scenario. *Kinsey* reads §508.010.4 expressly to allow joinder of multiple defendants in a single action even if venue is *not* proper as to one defendant, if the joinder is otherwise proper because of common liability. This is because the place of the first injury to the plaintiff now controls. Joinder of a second-injury-causing, commonly-liable defendant from an otherwise improper venue does not contravene §508.010.4. Thus, *Kinsey* concludes that "[t]here is no longer conflict between the venue statute and Rule 52.05(a), because Rule 52.05(a) is not the vehicle that expands or limits venue (as required by Rule 51.01 (A-19)) in these circumstances." *Id.* Venue need not be proper for each defendant when a plaintiff properly joins two defendants in a single action even when venue is improper as to one of the defendants.

Obviously, *Kinsey* found that §508.010 expressly permits what *Turnbough* denied – suits against multiple defendants to be joined in a county in which venue is not proper as to one defendant.

None of the cases Abbott cites deal with a case in which multiple properly joined plaintiffs sue in one of two statutorily sanctioned venues. Nor, of course, do they deal with the plain language of the venue statute at issue here. The language of the statute, the policy choices furthered in the cases, the value of efficient trials of properly joined cases, and the convenience-to-the-defendant basis for venue rules all point in a single direction: Where

multiple properly joined plaintiffs bring an action and sue a single defendant in a county in which venue is proper as to the defendant, venue is proper for all properly joined plaintiffs.

C. Rule 51.05 does not apply to this case.

"Venue in Missouri is determined solely by statute. Chapter 508 sets out the provisions that control venue." *Rothermich*, 816 S.W.2d at 196. Rule 51.05 (A-20) states: "**These Rules shall not be construed to extend or limit** the jurisdiction of the courts of Missouri, or **the venue of civil actions therein** [i.e., in the courts of Missouri]." (Emphasis added to show application to venue issues). Thus, given the legislature's right to control venue, Rule 51.05 says no more than this – that the Rules of Civil Procedure cannot expand or contract statutory venue rules.

Contrary to Abbott's assertions, Respondent is not using the joinder provisions to impermissibly "expand" venue. The statute directs that the "action" controls the venue analysis. This action is one invited by the rule permitting joinder. The venue statute makes venue proper as to Abbott in either the City of St. Louis or St. Louis County, if the action is one permitted under the Rules. As discussed, the law provides that there may be more than one proper venue in a case where multiple plaintiffs are joined against a single defendant.

To believe as Abbott would have this Court believe – that a chosen venue must be proper as to each plaintiff-defendant pair in a given case – would require adding words to the statute that do not exist. Courts may not "read into a statute a legislative intent contrary to the intent made evident by the plain language." *Keeny v. Hereford Concrete Prods., Inc.*, 911 S.W.2d 622, 624 (Mo. banc 1995). When one gets into the business of adding words

to a statute – as Abbott's position requires – because one thinks the statute needs them, the choice of the words added necessarily depends on the outcome the word-adder hopes to achieve. Indeed, if the legislature intended what Abbott now suggests, it would have actually said so. As House Bill 460 shows, the legislature knows how to say what it means on this subject.

Where the venue statute can be read to permit two venues, proper joinder of plaintiffs does not extend or limit venue rules at all. Rather, because venue is proper as to Abbott under §508.010.4 and .5, Rule 52.05 "is not the vehicle that expands or limits venue (as required by Rule 51.01) in these circumstances." *Kinsey*, 394 S.W.3d at 453.

D. There is no conflict between Section 508.010 and Rule 52.05(a).

Rule 52.05(a) permits joinder "in one action as plaintiffs if they assert any right to relief … in respect of or arising out of the same transaction, occurrence or series of transactions or occurrences and if any question of law or fact common to all of them will arise in the action…."

The issue whether the venue statute prevails over Rule 52.05(a) matters only if there is a facial conflict between the two. As discussed above, the legislature is presumed to know that its own stated policy expressed in Section 507.040, copied verbatim in Rule 52.05, applies when a defendant is otherwise in a proper venue. *See Turner*, 318 S.W.3d at 667-68 ("It is presumed that the General Assembly legislates with knowledge of existing laws.").

There is no conflict between Rule 52.05 and §508.010, only silence on the issue of joinder. Thus, where there is no conflict with the venue rules, Rule 52.05's goal of efficiency permits joinder and makes the City of St. Louis the proper venue here.

E. Abbott's Arguments Regarding a Litigation Crisis Have No Bearing on the Propriety of Venue.

Page after page of Abbott's brief suggests that this Court's interests ought properly to be focused on a supposed "litigation crisis" rather than on the law. Abbott's answer to the litigation crisis created in this case? It is not to challenge personal jurisdiction.[26] Rather, Abbott implies that trying this case once again in a Missouri trial court **ten miles** away would ameliorate the alleged "litigation crisis." Nothing Abbott suggests for this case would solve the so-called "crisis" it claims is caused by this case.

[26] The majority of cases Abbott cites as exemplars of the "litigation crisis" raise challenges to personal jurisdiction that appear to be impacted by this Court's recent decision regarding personal jurisdiction in the *State ex rel. Norfolk Southern Railway Co. v. Dolan* decision. SC95514, Slip. Op. (Mo. Feb. 28, 2017). Those issues are not present in this case because Abbott never raised a timely challenge to the fundamental issue of personal jurisdiction. That Abbott laments the fact that it failed to raise a challenge to personal jurisdiction when this case was filed should not afford it the right to infuse those policy arguments in this unrelated appeal.

Thus, Abbott's purported concern for the Missouri judiciary is nonsense; reversal would simply shift the case to another part of the Missouri judiciary – the judges in St. Louis County, where that Missouri court would expend further judicial resources. As discussed below, reversing a judgement after a trial was held, in a court that without dispute had both personal and subject matter jurisdiction, all in order to re-try the same case, is antithetical to the very purpose of venue statutes, which are designed to assure a convenient and orderly forum for litigation at the outset.

To the extent that there are problems seen with the effect of Missouri statutes, those policy issues are best left to the legislature. As Judge Richter noted in his concurring opinion affirming the trial court's judgment, "[t]o the extent this practice is seen as a problem it is within the power of the Legislature to 'fix it.'" Slip.Op.27.

F. This Court Need Not Reach Abbott's Venue Arguments Because Abbott Has Not Shown Any Error Affecting the Merits of the Action.

Even assuming Abbott's re-write of the venue statute were allowed and venue was improper in the City of St. Louis, to prevail here Abbott must still show prejudice that affected the merits of the case for this Court to reverse the trial court's judgment.

Abbott is incorrect that it is not required to show prejudice affecting the merits to prevail here. Tellingly, Abbott's brief fails to mention Supreme Court Rule 84.13(b) and this Court's holdings that it "is governed by Rule 84.13(b) which states: No appellate court shall reverse any judgment unless it finds that error was committed by the trial court against the appellant materially affecting the merits of the action." *Heintz v. Woodson*, 758 S.W.2d 452, 454 (Mo. banc. 1988) (internal quotations omitted); *Lewis v. Wahl*, 842 S.W.2d 82,

84-85 (Mo. banc 1992) ("By both statute and rule, an appellate court is not to reverse a judgment unless it believes the error committed by the trial court against the appellant materially affected the merits of the action.").

Thus, regardless of the basis of a post-judgment appeal, venue or otherwise, a party must show outcome-determinative prejudice involving the merits of the case in order to warrant reversal of a trial court judgment. Outcome-determinative prejudice means that there is a "reasonable probability that the jury would have reached a different conclusion…." *State v. Warren*, 141 S.W.3d 478, 491 (Mo. App. E.D. 2004). "A reasonable probability is a probability sufficient to undermine confidence in the outcome." *Storey v. State*, 175 S.W.3d 116, 125 (Mo. banc 2005).[27]

Abbott presumes that among the non-jurisdictional errors, venue stands alone, immune from Rule 84.13(b). The only case that Abbott cites to support its argument is *Igoe v. Dep't of Labor*, 152 S.W.3d 284 (Mo. banc 2005). While it is true that in *Igoe* this Court accepted a post-judgment venue challenge, there is no indication that the Rule 84.13(b) issue was raised by any party, and no discussion of the issue is to be found. Even

[27] Federal courts have recognized that a challenge to a venue determination post-trial (as opposed to a pretrial extraordinary writ) will generally fail "by way of an appeal of an adverse final judgment because [the petitioner] would not be able to show that it would have won the case had it been tried in a convenient venue." *In re Volkswagen of Am., Inc.*, 545 F.3d 304, 318-19 (5th Cir. 2008) (citing *In re Nat'l Presto Indus., Inc.*, 347 F.3d 662, 663 (7th Cir. 2003) and FED. R. CIV. P. 61 (harmless error rule)).

Abbott acknowledges that this Court "did not conduct a prejudice analysis." Sub.App.Br.59. What remains clear is that (1) *Igoe* does not stand for the proposition that Rule 84.13(b) has no applicability in a venue case, and (2) under that rule the Court cannot reverse this judgment for venue or any other issue unless Abbott can show that it affected the merits of the action.

Abbott also argues that "a showing of prejudice is not required in the [venue] statute." Sub.App.Br.59. This is both unsurprising and irrelevant. The source of the requirement lies in Rule 84.13(b).

The thrust of Abbott's appeal argues that this case was tried in an improper venue, an allegation completely divorced from the merits of the case. Venue is a procedural provision that according to this Court is "but the means through which we seek to ensure the fair and orderly resolution of disputes and to attain just results. They are not ends in themselves." *Heintz*, 758 S.W. 2d at 454. The purpose of venue enunciated by the courts is to assure a convenient forum in which to resolve allegations.[28] *DePaul Health Ctr.*, 870 S.W.2d at 822.

[28] Compare the purpose of venue to jurisdiction, which describes the power of a court to try a case based on constitutional principles. *J.C.W. ex rel. Webb v. Wyciskalla*, 275 S.W.3d 249, 252 (Mo. banc. 2009). Venue simply relates to the locale where a trial will be held, "assumes the existence of jurisdiction and determines, among many courts with jurisdiction, the appropriate forum for the trial." *Nixon*, 282 S.W.3d at 365.

For that reason, because it "involves a procedural rather than a jurisdictional question, venue is a matter that goes to process rather than substantive rights." *Nixon*, 282 S.W.3d at 365 (emphasis added); *see also Bugg v. Rutter*, 466 S.W.3d 596, 604 (Mo. App. W.D. 2015) ("Mr. Bugg does not suggest, nor can we discern, how his alleged change of judge error affected the action's merits . . . . A party is entitled to no particular judge."); *Seals v. Callis*, 848 S.W.2d 5, 7 (Mo. App. W.D. 1992) ("Callis has shown no prejudice resulting from suit being filed and tried in his home county. This Court is enjoined by Rule 84.13(b) not to reverse any judgment unless it finds that error was committed against the appellant materially affecting the merits of the action.").

Thus, under applicable precedent, Abbott has suffered no substantive prejudice affecting the merits of this case and cannot establish otherwise. It should be noted that Abbott was not left without any vehicle to challenge the venue determination before trial. It is "well-established" that appellate courts accept "the use of an extraordinary writ to correct improper venue decisions of the circuit court before trial and judgment." *Nixon*, 282 S.W.2d at 365. Abbott availed itself of these procedures, but the writs were denied. As the Court of Appeals observed, "[b]oth this [c]ourt and the Supreme Court heard Appellant's arguments supporting its position that venue was improper in this case after the issue was fully briefed by both sides in the writ proceedings in both courts." Slip.Op.8. While denials of writs are not conclusive, those denials are informative on the presence-of-prejudice analysis.

Not only is it the law, it makes sense that the courts can correct venue errors (if any) at the outset of litigation, but that a showing of prejudice would be required post-trial. It

would be antithetical to the very purpose of venue provisions – to assure a convenient, logical and orderly forum for litigation – to reverse a trial on the merits in a court that had jurisdiction just so the parties and court system can litigate the case over again in another forum.

There is no dispute that the trial court had both personal and subject matter jurisdiction here. The outcome was a finding by a properly chosen jury in a trial before a qualified judge who conducted a fair trial that resulted in a finding that Abbott's product caused tragic injuries to Respondent. Thus, for Abbott to prevail on its prejudice claim, this Court would have to decide that it has no confidence in any City of St. Louis jury and/or trial judge such that holding a trial there, in and of itself, prejudices the merits of a case. It would have to conclude as a matter of law that a properly chosen jury which hears the same evidence in a trial before a qualified judge who conducted a fair trial would, more likely than not, produce a verdict for Abbott simply because that jury/judge sat in St. Louis County.[29]

[29] Abbott speculates that Respondent would not have won her case in any other venue. Sub.App.Br.59-60. Abbott cites to the fact that juries have found in its favor in three venues outside of Missouri. Abbott neglected to mention that it ended another trial (tried by the undersigned counsel) by settling the case during jury deliberations – a case tried in the U.S. District Court for the Eastern District of Missouri. More than half of the jurors in that case came from St. Louis County and the others came from other counties outside the City of St. Louis. Abbott also raises "many prejudices" to the courts and

No court can permit the law to conclude that prejudice occurs simply because of the location of a trial when all due process and legal guarantees are provided to the complaining party. If the legislature sees fit to change the venue statute so that fewer cases are filed there, for whatever reason, that certainly is within its prerogative. But for this Court to hold as Abbott asks this Court to hold is to create a *per se* rule that the juries/judges of the City of St. Louis are not to be trusted and that no one can ever receive a truly fair trial in that venue.

There is a reason Abbott cannot cite a single case to support its prejudice claim. No court has written off a particular venue and held, as a matter of law, that such venue does not offer litigants a fair trial.

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potential jurors. Sub.App.Br.62-63. Neither of the above arguments of course relate to the merits of this action as required by rule.

II.

Abbott's second point argues that it is entitled to reversal and remand because Respondent's case was improperly joined with other cases.

STANDARD OF REVIEW

While the meaning or interpretation of a rule or statute is reviewed *de novo*, denial of a motion to sever, which is what Abbott complains of here, is reviewed for abuse of discretion. *See Levey v. Roosevelt Fed. Sav. & Loan Ass'n*, 504 S.W.2d 241, 245 (Mo. App. 1973) ("Therefore, we hold the provision of Rule 52.05(a) and Rule 55.07 (A-28) were complied with, and that the trial court did not abuse its discretion in permitting a joinder of party plaintiffs, party defendants, and a joinder of claims."); *Wilson v. Bob Wood & Assocs., Inc.*, 633 S.W.2d 738, 743 (Mo. App. W.D. 1981). A discretionary ruling is presumed correct, and an abuse of discretion only occurs where the court finds that the ruling is clearly against the logic of the circumstances and so arbitrary and unreasonable that it shocks the sense of justice. *State ex rel. Sago v. O'Brien*, 827 S.W.2d 754, 755 (Mo. App. E.D. 1992) ("It is presumed that a discretionary ruling is correct. Judicial discretion will be found to be abused only when the ruling is clearly against the logic of the circumstances and is so arbitrary as to shock the sense of justice."). Certainly there was no abuse of discretion here and Abbott does not make any argument to show one. As shown below, whether viewed under an abuse of discretion or *de novo* standard, there was no error here because joinder was plainly proper.

A. Introduction

The usual grounds for a claim of misjoinder and related demand for severance – that trying all of the cases in a single trial will prejudice the defendant – are absent here. The trial court severed this case for trial as permitted by Rule 52.05(b) and as anticipated by ¶31 of Plaintiffs' Petition. LF37. No prejudice could have resulted from the trial court's decision to try Respondent's case alone.

Abbott therefore must assert that the pleadings – the "action" – were insufficient to permit joinder and that the trial court erred in overruling Abbott's motion to sever based on those pleadings.

Abbott's claim for improper venue depends on the conclusion that joinder of these cases was not proper. This is because Abbott's argument is predicated on the notion that, due to misjoinder, this case was tried in an improper venue. Thus, the only prejudice that could have resulted from the alleged joinder error was related solely to venue. Abbott admits this. Sub.App.Br.74-75. As the response to Point I shows, Abbott's arguments for reversal regarding joinder run afoul of Rule 84.13(b) for the very same reasons that Abbott's venue argument fails.

B. Joinder Was Proper Under Rule 52.05.

Rule 52.05 permits joinder here. Missouri Rule 52.05 is derived from Federal Rule of Civil Procedure 20 (A-31). The interpretation of a Missouri rule generally should be "in accord with the interpretation of the federal rule from which it came." *State ex rel. Farmers Ins. Co. v. Murphy*, 518 S.W.2d 655, 662 (Mo. banc 1975). Speaking to FED. R. CIV. P. 20, *United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 724 (1966) said: "The impulse is

toward entertaining the broadest possible scope of action consistent with fairness to the parties; joinder of claims, parties and remedies is strongly encouraged." *See also* 7 FED. PRAC. & PROC. CIV. §1660 (3d ed.) (A-59) ("The general philosophy of the joinder provisions of the federal rules is to allow virtually unlimited joinder at the pleading stage but to give the district court discretion to shape the trial to the necessities of the particular case.").

The Rules of Civil Procedure seek a common purpose – to create as much efficiency as possible for the judiciary and the parties while preserving the rights of the parties to litigate their case without the potential prejudice of other, unrelated cases being litigated at the same time.

Rule 52.05(a) expressly provides that joinder is proper even if the relief sought is different for the joined plaintiffs and anticipates the need for separate trials once the efficiencies of addressing common questions of law or fact in the case are achieved. The rule specifically provides:

> **Permissive Joinder.** All persons may join in one action as plaintiffs if they assert any right to relief … severally… in respect of or arising out of the same transaction, occurrence or series of transactions or occurrences and if any question of law or fact common to all of them will arise in the action. … A plaintiff or defendant need not be interested in obtaining or defending against all the relief demanded….

Because the efficiencies sought by Rule 52.05(a) are maximized at the beginning of a properly joined action, the petition determines whether parties are properly joined. In

deciding a motion to sever, courts examine the "face of the [petition] by which we must decide the [motion to sever] question…." 7 FED. PRAC. & PROC. CIV. §1653 (3d ed.) (A-34).[30]

[30] Again, review is for abuse of discretion. Abuse of discretion occurs if a ruling shocks the conscience. Three judges have looked at this issue (not to mention all the appellate judges who examined and rejected writs in this case) and determined that joinder was proper. If abuse of discretion occurs only when the ruling is "clearly against the logic of the circumstances and is so arbitrary as to shock the sense of justice," it is difficult to conclude that three learned jurors each issued shock-the-conscience rulings. *O'Brien*, 827 S.W.2d at 755.

Judge Shaw of the United States District Court for the Eastern District of Missouri took the first look at the joinder issue in reviewing a motion to remand the case after Abbott removed it. He concluded that the pleadings presented "common questions of law and fact" that "are likely to arise in this case, including the causal link between Depakote and birth defects, whether defendant knew of the alleged danger of birth defects, and the terms of any express or implied warranties given by defendant." LF2223. The court held that "Plaintiffs' claims are sufficiently related to support joinder in this case." *Id.* Judge Heagney reexamined the joinder issue at Abbott's renewed insistence and concluded that severance was not proper. LF475-84. Both this Court and the Supreme Court subsequently refused an opportunity to disturb this ruling by extraordinary writ. And finally, Judge

The two requirements for permissive joinder under Rule 52.05(a) are met if plaintiffs can collectively aver any right to relief based on: (1) common questions of law or fact (2) in respect of (i.e. related to) … the same transaction, occurrence or series of transactions or occurrences. The commonalities need not be absolute:

> The rule does not require that *all* questions presented by each plaintiff be common; it is enough if there is *any* common question, *and* the wrongful quality of either defendant's act is a question common to both claims. No doubt the common question must be one of substantial litigious importance.

Levey, 504 S.W.2d at 247 (emphasis added). As *Levey* correctly notes, "[t]he test suggested by these terms are vague and unclear." *Id.* Suggesting a test, *Levey* holds that the "[c]ement or unity justifying joinder may be found from (1) a common scheme or design, or (2) the fact that all acts or conduct are more or less consciously directed toward or connected with some common core, common purpose, or common event." *Id.*

Dally, a recent case from this Court, seems to speak more expansively of Rule 52.05(a)'s use than does *Levey*. *State ex rel. Nixon v. Dally*, 248 S.W.3d 615, 617 (Mo. banc 2008). *Dally* holds that the "definition of 'series' does not require that the events be related to a common cause. Rule 52.05(a) requires that the series of occurrences be related by a common question of law or fact…." *Id.* One could argue that *Levey* essentially adopted a predominance analysis similar to that required under Rule 52.08(b)(3) (A-24)

Ohmer found these cases were properly joined in denying Abbott's renewed motion to sever on the eve of trial. LF2038.

for class actions (requiring "substantial litigious importance") and that *Dally* requires less: common questions of law or facts that are – as between the plaintiffs – related even if not predominant.

The serial sale of the same product by this single defendant to these plaintiffs is, under *Dally*, a related series of transactions/occurrences. "The common meaning of series is a "group of ... events ... succeeding in order and having a like relationship to each other," which can include events that are in "temporal succession." *Id.* at 617; *see also In re Prempro Prods. Liab. Litig.*, 591 F.3d 613, 622 (8th Cir. 2010) ("As stated in *Mosley v. Gen. Motors Corp.*, 497 F.2d 1330 (8th Cir. 1974): 'Transaction' is a word of flexible meaning. It may comprehend a series of many occurrences, depending not so much upon the immediateness of their connection as upon their logical relationship.").[31]

[31] The *Prempro* case involved a question of whether the plaintiffs' claims were fraudulently misjoined, rather than whether they were properly joined. The *Prempro* court found the defendant had not met its burden in showing that the plaintiffs' claims were "egregiously misjoined." *Id.* at 623. The court also concluded that the "litigation is likely to contain common questions of law and fact," including the "causal link between HRT drugs and breast cancer." *Id.* The discussion of the facts of that case and joinder requirements are instructive here. In fact, the U.S. District Court for the Eastern District of Missouri, in ruling that joinder was appropriate in this case, specifically found that Abbott's argument regarding joinder was "weaker than that rejected by the Eighth Circuit

Unlike *Dally*, this is a single defendant case. The plaintiffs all aver that Abbott's drug, Depakote, caused their birth defects. The petition pleaded as to each and every plaintiff that "Defendant's Depakote was defectively designed, inadequately tested, dangerous to humans and [the] unborn and lacked proper warnings as to the true danger associated with its use, and Plaintiffs suffered injury as a result of the mother's ingestion of Depakote." LF37-44. Plaintiffs averred that their case presented "common questions of fact and law concerning, *inter alia*, what information Abbott possessed concerning the harmful effects, what information it elected to disclose to physicians and patients about those harmful effects, and what information they were required by law to disclose about those effects." LF46. Indeed, the petition outlined 14 paragraphs of common factual claims regarding Abbott's knowledge and warning failures. Of the 113 paragraphs in the petition, all but the 24 that describe the individual plaintiffs apply to every plaintiff's case; stated differently, all the substantive pleadings are common. On the face of the pleadings, these cases are properly joined.

Specifically, on the theory submitted to the jury, all plaintiffs pleaded (among other causes of action) products liability based on a failure to warn theory. The claim was that all the injuries these plaintiffs suffered were within the narrow family of effects (birth defects) the significant potential about which Abbott knew and yet failed to warn.

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in *Prempro*. Plaintiffs' claims here are more logically connected to one another than the *Prempro* plaintiffs." LF2223.

The Court of Appeals confirmed that the joined plaintiffs' allegations were sufficiently related and gave rise to common questions of law and fact in affirming the trial court's judgment. Indeed, the Court of Appeals noted that the propriety of joinder was "readily apparent because of the common factual question as to the origin of plaintiffs' injuries." Slip.Op.5. The Court of Appeals further stressed that this case involves one defendant, the only manufacturer, seller, and marketer of the product at issue. *Id.* at 6. In addition, the plaintiffs made the same allegations stemming from Abbott's conduct towards risk information about its drug, including what "information Appellant possessed concerning Depakote's harmful effects and what information Appellant elected to disclose…and what information Appellant was required by law to disclose." *Id.* The Court of Appeals concluded that the plaintiffs showed "significant substantive commonalities directly related to the central issue in this case, Appellant's negligent dissemination of its drug Depakote." *Id.* at 7. That Abbott can identify differences in the individual claims is not the test. *Id*. at 7-8.

Thus, unlike some products liability claims, a failure to warn claim in this context broadly encompasses the full range of risks for which warnings should be given. And as to pregnant women, a physician prescribing a drug to or permitting its continued use with such a patient is required to consider the full range of defects warned against, not a specific defect that manifests itself after birth. Dr. Jacoby so testified. For this reason, Abbott's attempt to claim that the Plaintiffs pleaded different specific manifestations of birth defects resulting from the exposure to Depakote is unavailing as a rationale to require severance at the pleading stage. Discovery of Abbott's knowledge is a common fact as to each plaintiff

even if the specific type of birth defect that occurred is different. (In fact, general liability discovery directed to Abbott proceeded as to all plaintiffs in conjunction here.) It is the common failure of Abbott to warn adequately of all of these potential defects of which it was aware that is the common question of fact that unites the claims under Rule 52.05(a). And it is Abbott's liability for the full range of birth defects its Depakote causes that provides the common question of law that further supports joinder. That Abbott's warning changed over the years does not render joinder improper, as the trial court's decision to try the cases separately removes the differences that might otherwise confuse a jury.

Even applying the relatively more stringent test in *Levey*, the case proceeds from Abbott's acts that were "more or less consciously directed toward or connected with some common core, common purpose, or common event" – that is, Abbott's decision not to provide adequate warnings to all of the plaintiffs' physicians of the birth defect dangers of which it was aware.

C. Rule 52.05 Contemplates Single Trials of Properly Joined Cases.

The trial court's decision to try Respondent's case separately does not undermine the propriety of joinder. Abbott's circular argument that the fact that Respondent's claim was tried separately is proves improper joinder entirely disregards the language of Rule 52.05. Rule 52.05 expressly provides that joinder is proper even if the relief sought is different for the joined plaintiffs and anticipates the need for separate trials once the efficiencies of addressing common questions of law or fact in the case are achieved:

> (b) **Separate Trials--Protective Orders.** The court may … order separate trials or make other orders to prevent delay or prejudice.

Numerous courts have held that joinder is proper in pharmaceutical cases, and that it is proper to try joined cases one at a time. For example, a number of related Depakote cases are pending before the United States District Court for the Southern District of Illinois. *See In re Depakote Cases*, 12-cv-52-NJR-SCW.[32] One case has since been tried in that court and another is scheduled for May 2017. Other courts have held that the joinder of plaintiffs who were allegedly injured by the same product is proper. *See, e.g., Gracey v. Janssen Pharms.*, No. 15-cv-407, 2015 U.S. Dist. LEXIS 57990, at *12 (E.D. Mo. May 4, 2015) (granting a motion to remand and finding that joinder of 64 plaintiffs exposed to Risperdone was proper under Rule 20 (A-31)); *Fahnestock v. Boehringer Ingelheim Pharms. Inc.*, No. 16-cv-1013, 2016 U.S. Dist. LEXIS 109812, at *8 (E.D. Mo. Aug. 18, 2016)(finding that claims of sixty eight individuals alleging injury from use of anticoagulant drug "satisfy Rule 20(a)'s [permissive joinder] standard" "even if the end-of-the-line exposures occurred in different states and under the supervision of different

[32] Abbott removed a number of similar Depakote cases filed in Illinois under the Class Action Fairness Act, 28 U.S.C. 1332(d) (A-6), noting that the claims alleged common questions of law and fact. *See* Abbott's Notice of Removal, *In re Depakote*, 12-cv-52-NJR-SCW, Dkt. No. 2 at *6 (S.D. Ill. January 6, 2012). *See also In re Abbott Labs.*, 698 F.3d 568, 571 (7th Cir. 2012) (stating that the Class Action Fairness Act defines a "mass action" as "any civil action . . . in which monetary relief claims of 100 or more persons are proposed to be tried jointly on the ground that the plaintiffs' claims involve common questions of law or fact.").

medical professionals") (*citing Robinson v. Pfizer Inc.*, No. 16-cv-439, 2016 U.S. Dist. LEXIS 57174, at *6 (E.D. Mo. April 29, 2016) (holding the same with regard to allegations against pharmaceutical manufacturer)); *Jackson v. C.R. Bard, Inc.*, No. 16-cv-465, 2016 U.S. Dist. LEXIS 57896, at *9 (E.D. Mo. May 2, 2016) ("[T]he Court concludes that all of the plaintiffs' claims arise out of the same transaction or occurrence, or series thereof. Therefore, joinder of all ten plaintiffs' claims is proper under Rule 20(a)."); *Simmons v. Sketchers USA, Inc.*, No. 15-cv-340, 2015 U.S. Dist. LEXIS 46389, at *6-7 (E.D. Mo. April 9, 2015) ("Plaintiffs' claims meet Rule 20(a)'s standard. Because plaintiffs' allegations relate to defendant's design, manufacture, and marketing of Shapeups® - occurrences common to all plaintiffs – the Court concludes that their claims arise out of the same transaction or occurrence or series thereof. That remains true even if plaintiffs were injured in different states and their injuries range in severity and type, as their claims are all reasonably related."); *J.C. v. Pfizer, Inc.*, 2012 U.S. Dist. LEXIS 136791, at *26 (S.D.W.V. Sept. 25, 2012) (holding that 18 "Plaintiffs here assert sufficient allegations that their claims arise from the same occurrences, including Defendants' misrepresentations about Zoloft's safety").

Abbott points to some other cases suggesting that joinder of drug or other mass tort cases is not proper. None has precedential value as each is a trial court decision, often from another state. But even if each were precedential, Abbott's citation to them is also analysis-free as to the number of defendants, the disease range involved, and the extent of the alleged commonalities of fact and causes of action that were pleaded in those cases. For example,

Barton v. Express Scripts, Inc., No. 1022-CC10066, slip op. at 2-3 (Mo. Cir. May 17, 2011) involved, among other things, fourteen separate defendants.

Respectfully, Abbott's arguments regarding joinder and severance should not prevail here. As discussed above, two circuit judges in Missouri, as well as a federal court, and the Court of Appeals rejected Abbott's arguments that joinder was improper in this case. Respondent's claim was properly joined with that of other plaintiffs because her claims arose out of the same transaction or series of transactions or occurrences as others and the action was properly joined. Further, there certainly was no abuse of discretion in the denial of Abbott's motion to sever.

D. Abbott Cannot Show that the Alleged Joinder Error Affected the Merits.

Abbott simply proclaims that "there is no requirement for Abbott to show prejudice from the trial court's denial of Abbott's severance motion." Sub.App.Br.75. Again, there is no authority given for this Court to simply disregard its holdings that it "is governed by Rule 84.13(b) which states: No appellate court shall reverse any judgment unless it finds that error was committed by the trial court against the appellant materially affecting the merits of the action." *Heintz*, 758 S.W.2d at 452 (internal quotations omitted); *Lewis*, 842 S.W.2d at 84-85 ("By both statute and rule, an appellate court is not to reverse a judgment unless it believes the error committed by the trial court against the appellant materially affected the merits of the action."). Not only is joinder a procedural matter that could not have affected the merits of this case (as it was tried separately), the prejudice that Abbott asserts in connection with joinder relates to venue. Thus, for the very same reasons

discussed relating to venue, discussed in detail above, under Rule 84.13(b) this Court should not reverse the judgment.

In sum, Abbott's arguments raised in Point II of its appeal fall far short and should not serve as the basis for reversal of the trial court's judgment. Point II should be denied.

III.

STANDARD OF REVIEW

Abbott's arguments regarding the adequacy of the 2002 Depakote label also fail. Abbott's Point III assigns error to the trial court's failure to grant its JNOV and directed verdict motions.

To determine whether the evidence introduced at trial was sufficient to support the jury's verdict, an appellate court views the evidence in the light most favorable to the verdict and gives the prevailing party the benefit of all reasonable inferences. *See Moore v. Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. banc 2011). Any conflicting evidence, assertions or inferences are disregarded. *Keveney v. Mo. Military Acad.*, 304 S.W.3d 98, 104 (Mo. banc 2010). The judgment will only be reversed if there is a complete absence of probative facts to support the jury's conclusion. *Id.*

A. Introduction

Abbott does not challenge the instructions given to the jury. Rather, it argues that no matter what the evidence was, the jury should never have been given the opportunity to consider the adequacy of Abbott's warnings at all. This argument disregards established Minnesota law, which not surprisingly holds that the adequacy of a warning is a fact issue that must be resolved by the jury. *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1301 (D. Minn. 1988).

B. The Adequacy of a Warning is a Fact Issue for the Jury and Minnesota Law Supports the Jury Submission.

Minnesota law on failure-to-warn issues in a products liability setting is well established. In general, a supplier has a duty to warn users of a product if it is reasonably foreseeable that an injury could occur in its use. *Balder v. Haley*, 399 N.W.2d 77, 81 (Minn. 1987). The duty to warn includes the duty to give adequate instructions for the safe use of the product. *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 787 (Minn. 1977). And "where the manufacturer or the seller of the product has actual or constructive knowledge of danger to users, the seller or manufacturer has a duty to give warnings of such dangers." *Id.* at 788 (citing *Hill v. Wilmington Chem. Corp.*, 156 N.W.2d 898 (Minn. 1968)).

Like Missouri, Minnesota has adopted the learned intermediary doctrine, pursuant to which a manufacturer's duty to warn in the prescription drug setting is directed toward prescribing physicians, rather than patients. *Todalen v. U.S. Chem. Co.*, 424 N.W.2d 73, 79 (Minn. App. 1988), *overruled on other grounds by Tyroll v. Private Label Chem., Inc.*, 505 N.W.2d 54 (Minn. 1993) ("A manufacturer of prescription drugs can satisfy its duty to warn by supplying the prescribing physician with an adequate warning of hazards and risks attendant in the use of the medication."). Thus, a focus of adequate warnings is the physician's knowledge (or lack thereof) as a result of the warning.

Minnesota law recognizes "the flexible nature of the manufacturer's duty to warn of risks 'which it could discover through the exercise of reasonable care.'" *Huggins v. Stryker Corp*, 932 F. Supp. 2d 972, 989 (D. Minn. 2013) (quoting *O'Hare v. Merck & Co.*, 381 F.2d 286, 291 (8th Cir.1967)). "[P]ublic policy demands that greater duties of care be placed on manufacturers in order to protect consumers from the risks of harm to life and health." *Harmon Contract Glazing, Inc. v. Libby-Owens-Ford Co.*, 493 N.W.2d 146, 150

(Minn. App. 1992). Abbott had a duty to acquire knowledge about Depakote and to update its label. *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009). "[B]y maintaining this information, the manufacturer is in the position to most effectively reduce or eliminate risk." *McCormack v. Hankscraft Co.*, 154 N.W.2d 448, 450 (Minn. 1967).

Thus, "to be legally adequate, the warning should (1) attract the attention of those that the product could harm; (2) explain the mechanism and mode of injury; and (3) provide instructions on ways to safely use the product to avoid injury." *Gray v. Badger Min. Corp.*, 676 N.W.2d 268, 274 (Minn. 2004). Minnesota law holds Abbott "to the skill of an expert in its particular field of endeavor, and [Abbott] is obligated to keep informed of scientific knowledge and discoveries concerning that field." *Huggins*, 932 F. Supp. 2d at 987; *Karjala v. Johns-Manville Prods. Corp.*, 523 F.2d 155, 159 (8th Cir. 1975). This is not a passive duty. Abbott cannot be willfully indifferent to Depakote's risks, nor downplay their significance. *See Hodder v. Goodyear Tire & Rubber Co.*, 426 N.W.2d 826, 836 (Minn. 1988). "Both a manufacturer's duty to be informed of current scientific knowledge and a manufacturer's duty to exercise reasonable care and foresight to discover a danger in his product is relevant to whether a manufacturer knew or should have known of the risks in its product." *Willmar Poultry Co. v. Carus Chem. Co.*, 378 N.W.2d 830, 837 (Minn. App. 1985).

Thus, the knowledge that Abbott possessed carried with it a duty to amend its warnings with information about risks of which it learned. This is a continuing duty to update warnings where there is "knowledge of a problem with the product, continued sale or advertising of the product, and a pre-existing duty to warn of dangers associated with

the product." *Hodder*, 426 N.W.2d at 833. "In certain cases, 'reasonable care' might require a manufacturer to extrapolate from existing medical literature or conduct tests to discover potential risks when the medical literature contains clues or red flags that the manufacturer's desired course of action is dangerous." *Huggins*, 932 F. Supp. 2d at 989. This means that "[t]he manufacturer's duty to warn users of the potential danger…is commensurate with its actual knowledge of the risk involved to those users or the knowledge constructively imparted on it by available scientific or other medical data." *Karjala*, 523 F.2d at 159 (quoting *O'Hare*, 381 F.2d at 291).

These legal rules are founded on settled law that because "manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge" it "has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth*, 555 U.S. at 570-71, 578-79. "State tort suits [and] … [f]ailure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id.* at 579.

Minnesota law agrees. "[T]he manufacturer does have a far better opportunity than the ordinary practitioner to know and understand how and when its own product should be used." *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 887 (Minn. 1970). The "how and when" of Depakote's use in a pregnant woman (only as a last resort) is a focus of this case and the root of the claim that the warnings Abbott provided were inadequate because they

omitted important information, were fundamentally inaccurate and purposefully misleading.

Launching into a re-argument of its view of the facts, Abbott argues that its label was adequate "as a matter of law," despite the evidence adduced at trial that the warning was outdated, that it failed to include critical information, that it misstated Abbott's knowledge, and that the prescribing physician testified that this made a critical difference to his decision to prescribe the drug. No case supports Abbott's assertion that the warning here could be deemed adequate as a matter of law; in fact, courts applying Minnesota law have noted only a circumstance "such as where a plaintiff 'fails to identify any piece of information that would have convinced any [physician] to alter the recommended course of treatment with regard to the plaintiff." *In re Levaquin Prods. Liab. Litig.*, 726 F. Supp.2d 1025, 1034 (D. Minn. 2010) (citing and quoting *In re Orthopedic Bone Screw Litig.*, No. 3-96-1095, 1999 WL 628688 at *15 (D. Minn. March 8, 1999)).

Essentially, Abbott asks this Court to consider only the facts supporting its argument that its warning was adequate and to disregard any and all evidence that it was not. Not only does this turn the applicable standard of review upside-down, Abbott's adequate-as-a-matter-of-law argument also ignores that "issues such as the adequacy of the warning, breach of duty and causation remain for jury resolution." *Balder*, 399 N.W.2d at 81; *accord Kociemba*, 680 F. Supp. at 1301 ("The adequacy of the warning must be resolved by the factfinder."); *Gray*, 676 N.W.2d at 279 ("[W]e conclude that any question about the adequacy of Badger Mining's warning is for the jury.").

The evidence introduced at trial supports the jury's finding that Abbott failed to

provide an adequate warning to prescribing physicians like Dr. Jacoby. Abbott's knowledge about the risks of Depakote, the factual inaccuracies and omissions in the Depakote label, and the impact that this had on the prescribing physician in this case, Dr. Jacoby, are detailed above. There was more than enough evidence that the warning was inadequate and that this led to Respondent's exposure to the drug. These issues were for the jury's resolution. Slip.Op.13 (citing *Balder*, 399 N.W.2d at 81).

Abbott's brief tries to create an impression that holding that the adequacy of its warning is a fact question is somehow a novel one. Not surprisingly, Abbott fails to mention that including the trial court and the Court of Appeals in this case, every single court that has considered Abbott's arguments – the same arguments that it makes in this appeal – that the Depakote label was "adequate as a matter of law" has rejected them. *See, e.g., Z.H. v. Abbott Labs., Inc.*, 14-cv-0176, 2016 U.S. Dist. LEXIS 135792, at *18-19 (N.D. Ohio Sept. 30, 2016) ("[T]his Court is unaware of any court holding that such a [black box] warning is per se adequate as a matter of law. Rather, courts must consider the adequacy of the warning in light of the known risks.[33] Neither is the warning label *per se*

[33] *Accord B.F., et al., v. Abbott Labs., Inc.*, 12-cv-01760-CAS, 2016 U.S. Dist. LEXIS 42935, at *10 (E.D. Mo. March 31, 2016) (applying Missouri law) (that the Depakote label advised of a risk of spina bifida "does not necessarily render the Depakote warning label adequate as a matter of law. There is still a question of fact whether the warning was informationally deficient. In particular, it is questionable whether warning the patient of a 1 to 2 percent chance of having a baby with spina bifida if taking Depakote

adequate if the label indicates that the FDA assigned a Category D designation to the drug.").[34]

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fulfills Abbott's duty…to properly warn the doctor of the dangers involved."); *J.B. et al., v. Abbott Labs., Inc.*, 13-cv-326-DRH-SCW, 2014 U.S. Dist. LEXIS 51059, at *8-17 (S.D. Ill. April 4, 2014); *D.W.K., et al., v. Abbott Labs., Inc.*, 14-cv-847-NJR-SCW, 2015 U.S. Dist. LEXIS 108399, at *17-23 (S.D. Ill. Feb. 14, 2015) ("[T]he Court is not convinced that the mere fact that the label listed Depakote as a Category D drug and included a black box warning indicates that the label was adequate as a matter of law . . . . Plaintiffs have offered competent evidence to assert that the Depakote label was *not* clear, accurate and unambiguous as to Depakote's risks. Thus the Court concludes that determining whether Abbott's warning was adequate, and what language was required to make that warning adequate, is a question of fact for the jury."); *Rheinfrank et al., v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 771 (S.D. Ohio 2015) ("There is a question of fact as to whether the 2003 Depakote warning was inadequate. Plaintiffs have identified a number of alleged inadequacies in Abbott's warning . . . .").

[34] Abbott stresses that Depakote was a pregnancy "category D" drug. Dr. Jacoby testified that most AEDs were category C or D (to the extent Abbott implies that Depakote was the only category D AED, this is not correct), and that there was not much difference between those two ratings, as a physician should never assume a category C drug is safer than a category D. Tr. 1213, 1216. In 2002, none of the AEDs including Depakote were category X, a category that indicates a drug has been proven to cause damage to a fetus

1. Abbott's False Comparison

As shown previously, the Depakote label specifically contained discussion of the birth defect risks of antiepileptic drugs as a class (not only Depakote) and even made comparisons stating that "reports indicate a possible *similar association* [with birth defects] with the use of other antiepileptic drugs." SLF 3252 (emphasis added). Abbott's argument that it had no duty to compare itself to other drugs simply ignores the fact that Abbott's warnings voluntarily undertook a comparison with other drugs in its own warnings. And, as the Court of Appeals noted, the "fatal flaw" in Abbott's approach is portraying the foregoing as an "added" duty. Slip.Op.13.

Once Abbott undertook the comparison ("similar association"), its warning was required to state the comparison accurately.[35] *See Isler v. Burman*, 232 N.W.2d 818, 822 (Minn. 1975) ("It is well established that one who voluntarily assumes a duty must exercise

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and should not be used during pregnancy at all. Tr.1214-15. Abbott's expert neurologist, Dr. L. James Willmore, likewise testified that he never uses the pregnancy categories to indicate a gradation of risk. Rather the categories indicate that doctors should review the substance of the warnings. Tr.1515-16 (agreeing that pregnancy "categories don't determine anything as far as I'm concerned . . . . [i]t's the whole nature of the information [about] the drug that's of importance."); *see also* Tr.1520-22.

[35] Abbott tries to avoid this result by drawing the meaningless distinction that its label comparison "does not state that the degree of risk is identical; it simply states that there is a similar type of risk." Sub.App.Br.86.

reasonable care or he will be responsible for damages resulting from his failure to do so."); *Ironwood Springs Christian Ranch v. Walk to Emmaus*, 801 N.W.2d 193 (Minn. 2011)(same as to duty to third parties). The Court of Appeals noted:

> [A]s research revealed and it came to light that Depakote was the most dangerous drug for causing birth defects in comparison to other AEDs on the market, the jury found it reasonable that [Abbott] warn doctors of this fact about its own product, so doctors could make a truly informed decision about what AED to prescribe to their female patients of childbearing potential and only to prescribe Depakote if all others failed.

Slip.Op.13.

Though Abbott lists several cases[36] where a court held that a manufacturer had no duty to compare itself to its competitors, in none of those cases did a drug company voluntarily undertake a comparison and then falsely state the comparison or omit data that would have made the proper comparison possible to a learned intermediary. In fact, Abbott has brought these cases to the attention of other courts to no avail as they are inapposite. *See, e.g., Rheinfrank*, 119 F. Supp. 3d at 773-75 (noting Abbott's reliance on *Ackley* is misplaced because it did not involve warnings that included comparative information); *D.W.K.*, 2015 U.S. Dist. LEXIS 108399 at *24 (rejecting the same Abbott legal argument);

[36] *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990); *Smith v. Wyeth Labs., Inc.*, 1986 WL 720792 at *10 (S.D. W.Va. Aug. 21, 1986); *Pluto v. Searle Labs.*, 690 N.E.2d 619, 620-21 (Ill. App. 1997).

J.B., 2014 U.S. Dist. LEXIS 51059 at *14-15 ("The Court does not agree that [the cases Abbott cites] call for judgment in Abbott's favor as to Bonner's failure to warn claim."); *Z.H.*, 2016 U.S. Dist. LEXIS 135792 at *21-23 (same).

2. The 2002 Depakote Label Was Inadequate.

The jury found that Abbott did not adequately warn Dr. Jacoby of the risk of birth defects posed by Depakote. Without an adequate warning, prescribing doctors like Dr. Jacoby are incapable of making a fully informed prescription decision.

Dr. Jacoby testified that:

> With every medication you have to weigh the benefits, does it work, with the risks. If the benefits are good, that is great, and the risks are low, then you're going to end up with a good combination. If the benefits are good but the risks are way too high, then you're still going to end up with problems, so you wouldn't necessarily use that one.

Tr.1212. This is consistent practice with the part of the warning Abbott quotes in its brief advising doctors to weigh the "benefits of therapy against the risks." Sub.App.Br.29. What Abbott omitted, of course, was an accurate and up-to-date elucidation of those risks.

Abbott devotes pages to rehashing testimony from Respondent's mother that was read to the jury as well as selected excerpts from her medical records, in an effort to re-argue the facts and to shift the focus from what was at issue during the trial: Dr. Jacoby's prescribing decision. As discussed, Dr. Jacoby appeared at trial and testified to the reasons behind his prescription decision, his knowledge of the risks at the time, his understanding of his patient's medical condition and her medical records, how he counseled patients, his

understanding of the Depakote label, as well as testified that an adequate warning would have changed his prescribing decision. The jury ultimately was asked whether Abbott provided an adequate warning to Dr. Jacoby, an instruction that is not challenged in this appeal. Despite Abbott's attempts to re-argue its view of the evidence, even it must admit that Dr. Jacoby "testified that he would not have prescribed Depakote to Plaintiff's mother had he known of this greater risk." Sub.App.Br.25.

As demonstrated above, under Minnesota law Abbott had a duty to warn about what it knew and a duty to ensure that its label was neither false nor misleading. Abbott's 2002 Depakote label was both misleading because of what it did not say, and purposefully misdirecting because it said Depakote and other drugs presented "similar" risks and that sufficient data regarding the total incidence of birth defects was "not available." In directing the physician to calculate the risk/benefit analysis, Abbott misstated the risk of its drug both on its own and also when compared to its competitors. Had Abbott's warning provided this additional information, Dr. Jacoby testified he would not have prescribed Depakote. Tr.1185, 1209-10, 1222-25, 1232, 1313-14, 1320.

The jury here was properly presented with a fact issue as to the adequacy of a warning, an issue that Minnesota courts have expressly stated is one to be left to the finder of fact.

CONCLUSION

The trial court and the Court of Appeals simply applied settled law to deny Abbott's Motion for JNOV. Neither erred in doing so.

IV.

STANDARD OF REVIEW

Finally, Abbott challenges the punitive damages award. Whether sufficient evidence exists to support an award of punitive damages is a question of law, which the Court reviews *de novo*. *Banks v. Fluor Corp.*, 450 S.W.3d 308, 401 (Mo. App. E.D. 2014). "When reviewing whether a plaintiff has made a submissible case for punitive damages, an appellate court reviews the evidence in the light most favorable to submissibility, while disregarding all adverse evidence and inferences." *Williams v. Trans States Airlines, Inc.*, 281 S.W.3d 854, 870 (Mo. App. E.D. 2009). Only evidence that tends to support the submission should be considered. *Fluor*, 450 S.W.3d at 401.

A. Introduction

The standard of review for a punitive damages award is particularly noteworthy here because in addition to the Court of Appeals and the trial court in this case, every trial court that has been in a similar position to view the evidence of Abbott's conduct in a Depakote birth defect case has reached the same conclusion. Without exception, all have denied Abbott's motions for summary judgment and/or have allowed the submission of punitive damages to the jury, in the face of the same arguments that Abbott presents here. *See D.W.K.*, 2015 U.S. Dist. LEXIS 108399 at *48 ("Plaintiffs have presented sufficient evidence to support their claim that Abbott acted wantonly in failing to update the label information and failing to warn of certain risks all while aggressively marketing Depakote.

On the evidence presented by Plaintiffs, a reasonable jury could conclude that Plaintiffs are entitled to punitive damages.").[37]

It is worth observing that because the jury's punitive damages verdict for this catastrophically injured child yields a ratio of compensatory damages to punitive damages that is less than 2 to 1 (1.53-1), Abbott has no available argument that the award is excessive. Lacking that, and also any credible argument that the actual evidence submitted was insufficient to support the jury's verdict, Abbott resorts to repackaging its oft-rejected arguments that its warning was adequate as a matter of law. As discussed in more detail below, there is absolutely no legal support for a conclusion that Abbott's "box" warning is a bar to punitive damages, no matter the facts and no matter its conduct.

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[37] *See also B.F., et al., v. Abbott Labs., Inc.*, 12-cv-01760-CAS, 2016 U.S. Dist. LEXIS 47618, at *8 (E.D. Mo. April 8, 2016) ("Plaintiffs' evidence of Abbott's alleged dilution of Depakote's warning and its dissemination of misleading information associated with Depakote use during pregnancy creates a genuine issue of material fact regarding whether Abbott's actions rose to a level of culpable behavior."); *Rheinfrank*, 119 F. Supp. 3d at 760 ("The Court finds that Plaintiffs may pursue punitive damages under their negligence theory in accordance with [Ohio law]."); *Z.H.*, 2016 U.S. Dist. LEXIS 135792 at *38 ("Plaintiffs may pursue punitive damages under its state law fraud claim because the allegations and evidence create genuine issue of fact whether Defendants alleged misrepresentations on the safety of Depakote evidenced a conscious disregard of the rights and safety of persons.").

B. The Minnesota Punitive Damages Statute

Minnesota law allows for the imposition of punitive damages when there is clear and convincing evidence of a deliberate disregard for the rights or safety of others:

> (a): Punitive damages shall be allowed in a civil action only upon clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others.
>
> (b): A defendant has acted with deliberate disregard for the rights or safety of others if the defendant has knowledge of facts or intentionally disregards facts that create a high probability of injury to the rights or safety of others and
>
> > (1) deliberately proceeds to act in conscious or intentional disregard of the high degree of probability of injury to the rights or safety of others; or
> >
> > (2) deliberately proceeds to act with indifference to the high probability of injury to the rights or safety of others.

Minn.Stat. §549.20 (A-5).

"Awarding punitive damages furthers the state's interest in protecting its citizens from harm by deterring and punishing such conduct." *Hodder*, 426 N.W.2d at 837. "The state is not only concerned with compensating plaintiffs, but also ensuring that similar conduct does not harm others in the future." *Mrozka*, 482 N.W.2d at 812.

Further, the Minnesota punitive damages statute provides nine factors to guide the jury in measuring an award of punitive damages:

(1) The seriousness of the hazard to the public that may have been or was caused by the defendant's misconduct;

(2) The profit the defendant made as a result of the misconduct;

(3) The length of time of the misconduct and if the defendant hid it;

(4) The amount the defendant knew of the hazard and its danger;

(5) The attitude and conduct of the defendant when the misconduct was discovered;

(6) The number and level of employees involved in causing or hiding the misconduct;

(7) The financial state of the defendant;

(8) The total effect of other punishment likely to be imposed upon the defendant as a result of the misconduct. This includes compensatory and punitive awards to the plaintiff and other persons; and

(9) The severity of any criminal penalty.

§549.20.3 M.S.A. In agreement with the Minnesota Pattern Jury Instruction, the Court of Appeals held that "[t]hese nine factors are not exclusive or exhaustive. Out of the nine factors elucidated in Section 549.20.3, the parties submitted the first six to the jury for their consideration: seriousness of hazard; profitability; duration; awareness; attitude; and participation." Slip.Op.21; CIVJIG 94.10.

C. The Evidence In Support Of Respondent's Punitive Damages Award Is Overwhelming.

It is telling that Abbott does not address the actual evidence that was admitted as to its knowledge and its conduct. As discussed previously, Abbott was acutely aware that Depakote had an increased risk of birth defects versus its competitors and therefore was significantly more dangerous for use in women of childbearing age. Abbott was aware of studies showing the overall risk of birth defects with Depakote to be ten percent or even greater, consistently concluding that Depakote posed a higher risk of birth defects than its competitors, that the risk of spina bifida was significantly higher than the 1-2 percent stated in the label, and that Depakote posed a twentyfold increase in the risk of spina bifida over the background rate.

Before Respondent's conception, Abbott was even specifically advised that Depakote should not be used or should be avoided in women of childbearing potential unless there was no available alternative. Despite conducting no independent research or studies to evaluate Depakote's safety in pregnancy, Abbott spent $50-100 million per year marketing the drug. In the early 2000s, Abbott sought to "squeeze every dollar and every prescription" out of the market.[38] This in the face of acknowledgement that "safety in women" was one of the factors that "drives the AED market."[39]

[38] SLF2526 at 91-92; SLF2985; SLF3077.

[39] SLF2583 at 138-39.

As discussed above, Depakote was known internally as a "dirty drug" due to safety issues. Yet, Abbott's 2002 goals were to "expand Depakote use in women" and grow market share "or we will die."[40] Information relating to the risk of birth defects was regarded as an "obstacle" to sales and was "damaging to Depakote." Thus, not only did Abbott fail to provide accurate information and correct what was by 2002 (and earlier) misleading information provided to physicians, internal documents and depositions show that its strategy was to "expand the use of Depakote in women" and "maintain Depakote's position as a first line agent for women with epilepsy."[41]

Abbott's conduct in choosing not to disclose the information of which it knew caused Maddison grave injury: Dr. Jacoby testified that he would not have prescribed the drug to her mother. Taken together, the evidence is clear and convincing. Placed in the context of the six factors submitted to the jury:

- **Factor 1: Seriousness of the hazard to the public that may have been or was caused by Abbott's misconduct:** It is hard to imagine a hazard more serious than these birth defects. Labeling and promoting a drug as no more dangerous than competitors for the purpose of maintaining a marketing plan to

[40] SLF2524 at 58; SLF2529 at 160-61; SLF2530 at 161, 163, 166; SLF2531 at 166-67; SLF3100.

[41] SLF2529 at 159, 161; SLF2530 at 161; SLF2531 at 174-75; SLF2532 at 174-75; SLF3102; SLF3151; SLF2601 at 244, 248-49; SLF2602 at 248-249; SLF2574 at 72-73, 75.

maintain or even expand the number of people exposed to it is the very essence of deliberate indifference.[42]

- **Factor 2: Profitability of Abbott's misconduct**: The drive to increase sales was paramount at Abbott. It would be impossible to carry out a marketing plan of "first line" use in women or to expand use in women if the company had disclosed the extreme increase in danger.[43]
- **Factor 3: Duration of Abbott's misconduct**: The evidence showed that Abbott was aware of studies that contradicted its label and its marketing messages for many years.
- **Factor 4: Abbott's awareness of valproic acid's dangers and concealment of the misconduct:** Abbott's own documents show that birth defect information was an obstacle to sales and that this information led to the product being "under attack." The evidence also showed that Abbott had actual

[42] SLF2529 at 159, 161; SLF2530 at 161; SLF2531 at 174; SLF2532 at 174-75. *See also* SLF3102, SLF3151; SLF2601 at 244; SLF2574 at 72-75; SLF2575 at 75-76. *See also* Tr.1183-84, 1192-93, 1198-99, 1209-10; 1215-22.

[43] SLF2529 at 159, 161; SLF2530 at 161; SLF2531 at 174; SLF2532 at 174-175. *See also* SLF3102; SLF3151; SLF2601 at 244; SLF2574 at 72-75.

knowledge of the increased danger and chose not to warn about it or restrict the product's use.[44]

- **Factor 5: Abbott's attitude and conduct after discovery of the misconduct:** By way of example, Abbott reacted to studies showing the drug's increased risk by stating internally that the information was "damaging to Depakote." There was no evidence that Abbott made efforts to communicate this information, that such communication was even considered or that consideration was given to the potential damage to people that could result.[45]

[44] Tr. 1021-22. *See also* SLF2632; SLF3176-79; SLF2612 at 207, 212-13; SLF2549 at 850; SLF2557 at 242; SLF2565 at 107; SLF2611 at 201-04; SLF2612 at 207, 212-13; SLF2557 at 242; SLF2564 at 88; SLF2565 at 107; SLF2632; SLF3242; SLF2549 at 850; SLF2515 at 278-79; SLF2517 at 288-90; SLF2518 at 290, 314; SLF2519 at 314, 319, 327, 331; SLF2520 at 331-33; SLF2557 at 242, 303-05; SLF2558 at 306-07; SLF2591 at 229-30. Not only was this information not disclosed, Abbott's label instead falsely stated to physicians that sufficient data to determine the incidence of birth defects was "not available." Tr.1026-29; 1031-32; 1219-22.

[45] SLF2600 at 210; SLF2611 at 201-04; SLF2612 at 204, 207; SLF2530 at 166; SLF2531 at 166-168; SLF2571 at 113-14; SLF2572 at 116; SLF2586 at 166-67; SLF2587 at 167-69; SLF2632.

- **Factor 6: Number and level of employees involved in causing or hiding the misconduct:** The evidence shows that Abbott's knowledge and marketing plans reached the highest level of the company.[46]

The facts presented at trial provide clear and convincing evidence upon which the jury concluded that Abbott deliberately disregarded the safety of Maddison and other children born to women taking Depakote.

Following trial, the trial court reviewed the punitive damages award in light of the statutory factors and upheld it. The Court of Appeals likewise addressed all of Abbott's arguments and held:

> Consideration of the factors set forth in Minnesota's punitive damages statute leads us to believe the jury's award of punitive damages was warranted.
>
> . . .
>
> The facts presented at trial provide clear and convincing evidence upon which the jury could conclude Appellant deliberately disregarded the safety of Respondent and thus was entitled to have punitive damages assessed against it.
>
> The trial court "specifically reviewed the jury's $23 million punitive damages award against [Appellant]" in light of the factors set forth by the Minnesota punitive damages statute. The court held "[b]ased on the facts and evidence presented at trial, the Court finds that the jury's award of punitive

[46] SLF2529 at 160-61; SLF2530 at 161, 163, 166; SLF2531 at 166-67.

damages was supported by the evidence adduced at trial, in accordance with the statutory factors, and not excessive." We agree. Point IV is denied.

Slip.Op.22 (emphasis added).

In its brief, Abbott argues that the Court of Appeals "misapplied the applicable 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." Sub.App.Br.102. It is not clear what this complaint means, and there is no indication that this has any substantive significance, but it is simply not correct. Here are the Court's words: "[t]he facts presented at trial provide clear and convincing evidence upon which the jury could conclude Appellant deliberately disregarded the safety of Respondent and thus was entitled to have punitive damages assessed against it." Slip.Op.21.

In sum, the evidence was sufficient to support the submissibility of punitive damages. The finding and amount was for the jury to decide.

D. No Legal Bar to Punitive Damages Exists Here.

Abbott argues that the Court should disregard the evidence supporting the verdict and instead rule as a matter of law that because the label mentioned a risk of spina bifida and contained a "black box" warning, it cannot be liable for punitive damages under any circumstances. Leaving aside that this is a request to turn the standard of review on its head (consider only the evidence Abbott points to and disregard any evidence of Abbott's conduct or that the label was nonetheless inadequate), there is no legal authority for this

proposition. Quite the contrary, the courts that have been presented with this argument have not accepted it.[47]

As discussed, the trial court and the Court of Appeals correctly considered and applied Minnesota law and held that the facts and evidence presented at trial were sufficient for the jury to conclude that Abbott deliberately disregarded the rights or safety of others. Abbott says that even if this finding is correct, the punitive damages award is inconsistent with Minnesota law simply because its warning in a black box, in and of itself, wholly absolves it of punitive damages liability – no matter what the warning says or fails to say and no matter its own conduct, even including conduct that took place in the years after the placement of that box in 1996. The source of this "black box" exception to punitive

[47] *D.W.K.*, 2015 U.S. Dist. LEXIS 108399 at *44 (label's references to spina bifida not dispositive on the issue of punitive damages, "[t]he Court must still necessarily inquire whether Plaintiffs have presented evidence . . . which creates a genuine issue of material fact as to whether Abbott's action rose to a level of culpable behavior") (citing cases); *B.F.*, 2016 U.S. Dist. LEXIS 47618 at *7-10 (existence of black box warning and specific reference to spina bifida does not bar submission of punitive damages); *Z.H.*, 2016 U.S. Dist. LEXIS 135792 at *38 ("Plaintiffs may pursue punitive damages under its state law fraud claim because the allegations and evidence create a genuine issue of fact whether Defendants alleged misrepresentations on the safety of Depakote evidenced a conscious disregard of the rights and safety of persons.").

damages liability is a mystery. It is not in the Minnesota statutes, it is not in any federal law, and no case so holds.

To the contrary, with respect to this issue, the jury, the trial court, several different federal courts, and the Court of Appeals have all recognized that it is not the color of the box's border that determines the adequacy of the warning or Abbott's state of mind. It is the content of the warning, Abbott's avoidance of revealing the truth about Depakote, and Abbott's financial incentives that reveal its motives that justify punitive damages. Putting a black box around a patently false warning, and failing to update it for many years, actually heightens the evidence that Abbott acted with deliberate disregard for the safety of others rather than ameliorating it.

In an effort to liken this case to the Eighth Circuit's opinion in *In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161 (8th Cir. 2012) and denounce the trial court's ability to competently apply Minnesota law,[48] Abbott again creates its own made-up version of the warnings at issue and the alleged absolute importance of a black box warning.

In *Levaquin*, the Eighth Circuit's rationale for not upholding the jury's punitive damages award was predicated on the facts that:

[48] It should be noted that with respect to punitive damages under Minnesota law, the trial court did not engage in any novel analysis. It submitted a pattern jury charge to which there was no objection.

(1) notwithstanding the warning's inconspicuous nature within the last paragraph of multi-paragraph warning in the drug package insert, the warning was ultimately correct; and

(2) there was no record evidence to support a punitive damages finding and the allegation of financial motive was "mere speculation."

Id. at 1169-70.

Here, in stark contrast, Abbott's warning deliberately omitted critical data, made a patently false comparison with its competitors about the risk of birth defects, and falsely stated that there was not "sufficient data" regarding birth defects. There is substantial evidence that the warning given was inadequate and that Abbott was aware of its falsehood. Unlike *Levaquin*, the evidence is not that Abbott failed to bring an otherwise correct warning to the doctor's attention; it is that Abbott delivered a warning that omitted information and was false and misleading.

Nowhere does *Levaquin* stand for a broad proposition that a black box or any other particular form of warning serves as a legal bar to punitive damages; rather, it is that there must be sufficient evidence to support a finding of punitive damages. As the Eighth Circuit succinctly observed subsequent to its initial opinion, in a case that Abbott does not cite, "[w]e reversed the punitive damages award of $1,115,000 because [plaintiff] failed to present clear and convincing evidence that [defendant] deliberately disregarded the safety of Levaquin users." *In re Levaquin Prods. Liab. Litig.*, 739 F.3d 401, 403 (8th Cir. 2014). As shown above in detail, far from being "mere speculation" as in *Levaquin*, the facts and

evidence presented at the trial of this case demonstrated Abbott's deliberate disregard for safety.

Moreover, the other cases Abbott cites similarly fail to support Abbott's *de facto* position that a particular form of warning serves as a legal bar to punitive damages. Rather, like *Levaquin*, those cases hinge on whether there was sufficient evidence to support a punitive damages finding. *See Heston v. Taser Int'l, Inc.*, 431 F. Appx 586 (9th Cir. 2011) (affirming the district court's decision to vacate punitive damages award, as there was no finding upon which the jury could legally base a punitive damages award since jury found the defendant "TASER neither knew the risk of harm that it was creating nor . . . consciously disregard[ed] a scientifically knowable risk"); *Dudley v. Bungee Int'l Mfg. Corp.*, No. 95-1204, 1996 U.S. App. LEXIS 1267, at *7 (4th Cir. Jan. 31, 1996) (evidence was insufficient to support punitive damages award because it failed to rise to the level of willful and wanton negligence); *Toole v. McClintock*, 999 F.2d 1430, 1436 (11th Cir. 1993) ("We conclude that there was insufficient evidence of wantonness in this case to permit the jury to award punitive damages."); *Salvio v. Amgen, Inc.*, No. 11-cv-00553, 2012 U.S. Dist. LEXIS 19009, at *23 (W.D. Pa. Feb. 15, 2012) (dismissing punitive damages claim because plaintiff "failed to allege any conduct that would rise to the level of seriousness necessary for imposing punitive damages and to satisfy the pleading standard of *Twombly*, *Fowler*, and *Phillips*"); *Scheinberg v. Merck & Co., Inc., (In re Fosamax Prods. Liab. Litig.)*, 924 F. Supp. 2d 477, 490 (S.D.N.Y. 2013) (granting a motion for summary judgment because "[o]n the evidence presented by Plaintiff, no reasonable jury could conclude Plaintiff would be entitled to punitive damages"); *Ilosky v. Michelin Tire Corp.*,

307 S.E.2d 603, 619 (W. Va. 1983) (upholding trial court's dismissal of punitive damages claim because "the facts do not meet the willfulness, wantonness, or malice standard").

Neither the *Levaquin* opinion, nor any other case Respondent is aware of, serves as or even suggests a bar to punitive damages where the injury suffered by a plaintiff is mentioned in a warning label or a box, no matter the facts and no matter the defendant's conduct. The issue on appeal here is whether the evidence was sufficient to support submission of punitive damages to the jury. As shown above, it was.

E. The Evidence Relied Upon was Relevant to Plaintiff's Theory of Liability.

Abbott also contends that some of the evidence relied upon by the jury—the same facts and evidence carefully analyzed by the trial court and the Court of Appeals to uphold the punitive damages verdict—was not relevant. Abbott also objects to certain jury arguments. Sub.App.Br.99. Abbott never objected to any of the jury argument of which it now complains and, therefore, the point is waived. The "absence of an objection is fatal to the defendant's contention" on appeal. *State v. Kempker*, 824 S.W.2d 909, 911 (Mo. banc 1992). There is also no complaint on appeal to the admission of the evidence underlying the argument, nor any showing how this would in any way warrant reversal even if there were proper objections made to both the argument and the evidence.

For example, Abbott asserts that Dr. Cheryl Blume, one of Respondent's expert witnesses, never opined that Abbott should have warned about "Depakote's risk of birth defects compared to every other drug sold in the United States." Sub.App.Br 99. This is a strange assertion because there is no apparent reason she was required to do this, the issue was never raised at the trial court, and of course the comparison in Abbott's label and what

made a difference to Dr. Jacoby was the danger of Depakote as compared to other AEDs, to which she did testify:

> [T]he labeling in my opinion did not adequately reflect the landscape, if you will, in the literature of the studies that had addressed birth defects associated with Depakote…
>
> [T]he labeling really needs to describe the overview of those studies and note that across those studies the risks were -- the risks reported were generally or some metric greater with Depakote compared to other AEDs….
>
> [T]he labeling should also note the companion sentence to that type of finding, is that women should not be prescribed Depakote as a first line, but only if other therapies were -- failed to control their seizures or were associated with safety concerns that could not be tolerated.

Tr.1023-24. And Dr. Jacoby testified:

> Q. Okay. You were asked if in 2002 the Depakote warning label warned to only use Depakote if all other treatment options failed would you have followed that warning.
>
> A. That is correct.
>
> Q. And you were asked if you had been warned in 2002 that Depakote was the most teratogenic drug would you have described it for Tiffany. What was your answer?
>
> A. I believe it's no.

Tr.1313.

Abbott also seems to complain about the admission of evidence related to its marketing of Depakote. Abbott believes the only relevance to this evidence is whether Dr. Jacoby relied on it in prescribing Depakote in this case. In this case, evidence related to marketing was relevant for other purposes, such as to what Abbott knew and when it knew about the scope of Depakote's birth defect risks and its proper use in women of childbearing years and Abbott's conduct relating to punitive damages.[49] Second, the omissions in the label warnings had a marketing purpose, and whether that was so was relevant to an understanding of Abbott's motives in refusing to update the label language. *See In Re Diet Drugs Prod. Liab. Litig.*, 369 F.3d 293, 314 (3rd Cir. 2004) ("[E]xcessive concern with image and marketing … at the expense of making efforts toward determining whether they are safe could be probative as to whether [defendant] breached a duty of care towards the plaintiffs."); Slip.Op.24.

In sum, Abbott's catch-all challenges to jury argument to which it did not object, and evidentiary rulings made by the trial court, do not warrant reversal of the judgment.

F. Abbott's New Due Process Arguments Should be Rejected.

Abbott further argues that the punitive damages award was inconsistent with the Due Process Clause because Abbott somehow lacked any notice that a comparative warning was

[49] Every other court that has tried a Depakote birth defect case has admitted essentially similar evidence to what was introduced here. *See, e.g., D.W.K. et al. v. Abbott Labs., Inc.*, 87 F. Supp. 3d 916, 928 (S.D. Ill. 2015).

required under Minnesota law. Abbott raises this argument on appeal for the first time. Similar to its argument regarding the relevancy of certain evidence, Abbott never raised this argument below, and therefore the point is waived. *See Kempker*, 824 S.W.2d at 911.

Nevertheless, the Court of Appeals directly addressed the essence of Abbott's underlying argument:

> Appellant persists in its position it was enough that it just warned of the bottom line risk known since the early 1980s that Depakote could cause birth defects such as spina bifida. Appellant argues it did not have an *added* 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.
>
> ***The fatal flaw in Appellant's argument is this is not an added duty***. Rather, as research revealed and it came to light Depakote was the most dangerous drug for causing birth defects in comparison to other AEDS on the market, the jury found it reasonable that Appellant warn doctors of this fact about its own product, so doctors could make a truly informed decision about what AED to prescribe to their female patients of childbearing potential and only to prescribe Depakote if all others failed. However, Appellant's "2003 Psychiatry Sales & Marketing Tactical Execution Plan" actually stated its

> objective was "to maintain Depakote's position as a *first-line* agent for women with epilepsy, bipolar, and migraine." (Emphasis added.)
>
> Issues such as the adequacy of the warning, breach of duty and causation are for the jury's resolution. Balder, 399 N.W.2d at 81. The adequacy of the warning must be resolved by the factfinder. Kociemba v. G.D. Searle & Co., 680 F.Supp. 1293, 1301 (D. Minn.1988).

Slip.Op.13 (emphasis added).

As the Court of Appeals noted, "Minnesota law dictates [Abbott] cannot claim ignorance of Depakote's dangers known in the field of pharmaceuticals and teratogenicity. . . . The law dictates [Abbott] had a duty to be apprised of the developments in the growing knowledge in the scientific community of Depakote's serious dangers, and to adequately warn about them." Slip.Op.17-18. Holding Abbott responsible for a failure to provide an adequate warning hardly represents the trial court concocting a "novel theory of liability" or imposing any "additional duties." And it certainly does not constitute a due process violation.

Moreover, Abbott's argument that it did not receive "fair notice" of the standards under which Minnesota law assesses punitive damages is completely undermined by the fact that the statute explicitly lays out the guiding standards for the assessment of such damages. And the jury's instruction was in complete accord with the statute.

CONCLUSION

The ultimate question on appeal is whether there was sufficient evidence to support the jury's assessment of punitive damages. Abbott's arguments avoid the actual evidence presented at trial. In contrast, the trial court, as well as the Court of Appeals, thoroughly examined the facts presented at trial and correctly applied Minnesota law in upholding the jury's conclusion that there was clear and convincing evidence of Abbott's deliberate disregard in light of the prescribed statutory factors. Point IV should be denied.

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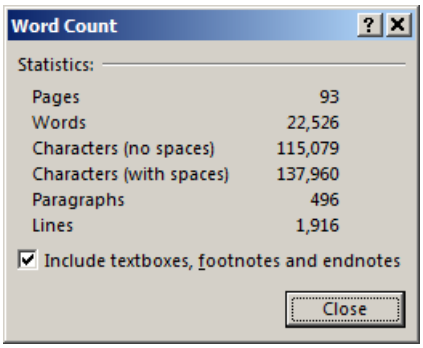

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CERTIFICATE OF SERVICE

I certify that in filing this document with the Supreme Court of Missouri through the electronic filing system an electronic copy of this document and attached Appendix was served on counsel named below on this 10th day of April, 2017, and the undersigned further certifies that he has signed the original and is maintaining the same pursuant to Rule 55.03 (a).

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