IN THE SUPREME COURT OF MISSOURI

E.N., individually and as next friend on behalf of her minor child N.N., *et al.*, *Plaintiffs/Appellants*, v. MIKE KEHOE, in his official capacity as Governor of Missouri, *et al.*, *Defendants/Respondents*.	No. SC100933 On Appeal from the Circuit Court of Cole County, No. 23AC-CC04530 Honorable R. Craig Carter

BRIEF OF DO NO HARM AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

Other Authorities

INTEREST OF *AMICUS CURIAE*

Do No Harm is a nonprofit membership organization that includes over 27,000 physicians, nurses, medical students, patients, and policymakers. Do No Harm is committed to ensuring that the practice of medicine is driven by scientific evidence rather than ideology. In recent years, the practice of biology-denying interventions, euphemistically known as "gender affirming care," has become more common despite the serious harm caused by those medical interventions and the complete lack of reliable evidence for any benefit caused by them. Indeed, Do No Harm has released a database demonstrating that nearly 14,000 minors were subjected to biology-denying interventions in the United States between 2019 and 2023. *See* Press Release, Do No Harm, Do No Harm Launches First National Database Exposing the Child Trans Industry (Oct. 8, 2024), https://perma.cc/JW24-3J6V. Part of Do No Harm's mission is to ensure that courts have a proper understanding of the dangers of these medical interventions and the lack of evidence supporting them. To that end, Do No Harm submits this brief to provide the Court with an accurate analysis of the lack of evidence justifying the use of puberty blockers, cross-sex hormones, and surgeries as treatments for gender dysphoria.

CONSENT OF THE PARTIES

Pursuant to Missouri Supreme Court Rule 84.05(f)(2), *amicus* certifies that all parties have consented to the filing of this brief.

JURISDICTIONAL STATEMENT

Amicus adopts the jurisdictional statement as set forth in Respondents' brief.

STATEMENT OF FACTS

Amicus adopts the Statement of Facts of Respondents.

ARGUMENT

"Gender affirming care" is a medical scandal. This purported "treatment" calls for a host of biology-denying medical interventions from puberty blockers to cross-sex hormones to genital surgeries. All this to treat a *psychological* condition. These interventions inflict grave harms, and there is no reliable evidence that they improve, much less resolve, gender dysphoria.

Some States, like Missouri, are doing something about it. Led by the scientific evidence, Missouri has prohibited the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria in minors. This decision is justified by the known harms of these interventions—including the sterilization of healthy boys and girls—and the complete lack of evidence that they do anything to resolve gender dysphoria.

The lack of evidence of benefit from these interventions has been established in every systematic review to analyze the question. These reviews—which represent the highest form of medical evidence—have been conducted by health authorities in Finland, Sweden, the U.K., and by expert researchers hired by the health authority in the State of Florida and the U.K.'s National Health Service. All of them have concluded that no reliable evidence establishes that these interventions help resolve gender dysphoria.

Appellants largely ignore not only these systematic reviews, but also the basic principles of evidence-based medicine. Instead, they rely on either doctors' clinical experience (the *lowest* form of medical evidence) or on individual studies that are

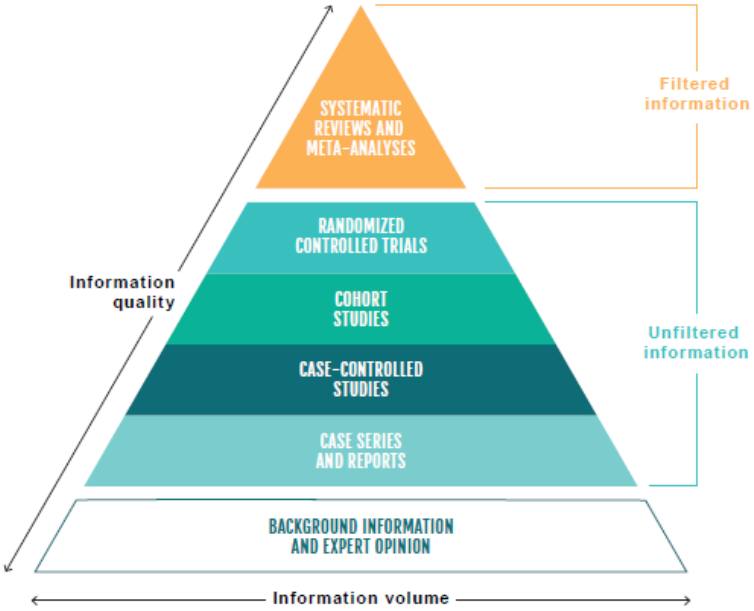
unreliable due to their high risk of scientific bias (as found in the systematic reviews described above). In addition, Appellants resort to conflating biology-denying interventions with treatment for conditions that carry *vastly* different risks and benefits. This too ignores principles of not only evidence-based medicine, but also common sense. Based on the medical evidence, Missouri was wholly justified in banning the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria in minors. The Court should affirm.

I. In The Practice Of Evidence-Based Medicine, Systematic Reviews Are The Highest Form Of Medical Evidence.

Although the proper practice of medicine is driven by evidence, not all medical evidence is created equal. Researchers have thus spent decades refining the process that clinicians use to assess the medical evidence supporting a particular medical intervention. That process—often referred to as the practice of "evidence-based medicine"—outlines a hierarchy of medical evidence based on the confidence a clinician can place in a particular source of evidence. *See* GORDON GUYATT, ET AL., USERS' GUIDES TO THE MEDICAL

LITERATURE: ESSENTIALS OF EVIDENCE-BASED CLINICAL PRACTICE 15 fig. 2-3, JAMAEVIDENCE (3d ed. 2015) ("Evidence-Based Medicine User Guide").

The "pyramid of standards of evidence" reflects the hierarchy of reliability for evidence in medicine:



See Independent Review of Gender Identity Services for Children and Young People: Final Report at 55, NAT'L HEALTH SERV. ENG. (Apr. 2024), https://perma.cc/KM5C-49EZ ("Cass Review") (reproducing graphic from *Levels of Evidence*, OPEN MD (July 17, 2021), https://openmd.com/guide/levels-of-evidence). As the pyramid shows, "systematic reviews" are at the top of the hierarchy of medical evidence. At the bottom of the hierarchy is clinical experience—*i.e.*, "the unsystematic observations of individual clinicians." Evidence-Based Medicine User Guide at 15.

Systematic reviews provide the greatest insight into the medical evidence underpinning a particular intervention. They account for all relevant studies, assess those

individual studies for areas of potential scientific bias, and thus show the *reliability* of the *entire* evidence base. *See id*. at 274-76. To assess bias in individual studies, researchers frequently use tools such as the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method. *See id.* at 16-17. In the GRADE system, researchers rate the evidence using specified criteria. "In the context of a systematic review, the ratings of the quality of evidence reflect the extent of our confidence that the estimates of the effect are correct." Howard Balshem et al., *GRADE Guidelines: 3. Rating the Quality of Evidence*, 64 J. CLINICAL EPIDEMIOLOGY 401, 403 (2011). This resulting rating of the evidence is either "high, moderate, low, or very low." Evidence-Based Medicine Users Guide at 16. The following definitions explain what the various levels mean:

> High Quality Evidence: "We are *very confident* that the true effect lies close to that of the estimate of the effect."
>
> Moderate Quality Evidence: "We are *moderately confident* in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different."
>
> Low Quality Evidence: "Our *confidence* in the effect estimate *is limited*: The true effect may be *substantially different* from the estimate of the effect."
>
> Very Low Quality Evidence: "We have *very little confidence* in the effect estimate: The true effect *is likely to be substantially different* from the estimate of effect."

Balshem, *supra*, at 404 tbl.2 (emphasis added). Thus, when evidence is deemed "low" or "very low" quality, that means researchers have "limited" or "very little confidence" that the results of the study reflect the truth; indeed, the truth may or *likely will* turn out "to be substantially different" from what such studies say.

Finally, after analyzing all relevant studies, the researchers will "summarize the results." Evidence-Based Medicine User Guide at 275. This process can include a quantitative synthesis or "meta-analysis" of data that provides an overview to clinicians. *See id.* at 275-76. The end result is a study of studies—a comprehensive look at the evidence on a given question that accounts for the reliability of the studies forming the evidence base.

In sum, systematic reviews are the most reliable form of medical evidence. And for several reasons, they are substantially more reliable than narrative reviews (such as a clinician's experiences presented at trial or in an expert witness report). First, unlike systematic reviews, narrative reviews "have no explicit criteria for selecting the included studies." *Id.* at 273. Therefore, narrative reviews can cherry-pick examples and individual studies—discussing only those that support their conclusions and ignoring those that do not. Systematic reviews do not suffer from this flaw.

Second, narrative reviews "do not include systematic assessments of the risk of bias associated with primary studies." *Id.* (emphasis omitted). Thus, narrative reviews may stress that several studies all support the same conclusion, but "[c]onsistent results are less compelling if they come from studies with a high risk of bias than if they come from studies with a low risk of bias." *Id.* at 283. Systematic reviews account for this principle; narrative reviews do not. For these reasons (among others), systematic reviews represent the highest form of medical evidence, and "optimally effective evidence-based practice dictates bypassing the critical assessment of primary studies and, if they are available, moving straight to the evaluation of rigorous systematic reviews." *Id.* at 4 (emphasis omitted).

II. Every Systematic Review Of Medical And Surgical Interventions For Minors With Gender Dysphoria Has Concluded The Evidence Is Weak.

Several entities and institutions have conducted systematic reviews to assess the evidence underlying the use of puberty blockers and cross-sex hormones as a treatment for minors with gender dysphoria. All have concluded that the evidence underlying medical interventions for gender dysphoria in minors is weak. Zero have come out the other way.

1. Finland. The first systematic review came in 2019 when Finland's Ministry of Social Affairs and Health completed its review of the medical evidence. In light of this evidence review, Finland's healthcare authority concluded that "gender reassignment of minors is an experimental practice." *Recommendation of the Council for Choices in Health Care in Finland (PALKO/COHERE Finland): Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors* at 8, PALVELUVALIKOIMA (Nov. 6, 2020), https://perma.cc/PF72-H654 (unofficial translation by the Society for Evidence Based Gender Medicine (SEGM)). This conclusion was based on the fact that "[t]he reliability of the existing studies" is "highly uncertain." *Id*. at 7.

2. The Cass Review Interim Report. Next, in 2020, the United Kingdom's National Institute for Health and Care Excellence (NICE) completed its review of the evidence for using puberty blockers and cross-sex hormones on minors with gender dysphoria to aid the Cass Review, an independent review commissioned by the United Kingdom's National Health Service. *See NICE Evidence Reviews*, THE CASS REV., https://perma.cc/APZ2-W8MS. The result was two separate systematic reviews—one for puberty blockers and one for cross-sex hormones. *Evidence Review: Gonadotrophin*

Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria, NAT'L INST. FOR HEALTH & CARE EXCELLENCE (Oct. 2020), https://perma.cc/F9FF-ZPFR ("NICE – Review of Puberty Blockers"); *Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria*, NAT'L INST. FOR HEALTH & CARE EXCELLENCE (Oct. 2020), https://perma.cc/U49T-JLGJ ("NICE – Review of Cross-Sex Hormones"). The review of puberty blockers concluded that the relevant studies were "all small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty using [a] modified GRADE" methodology. NICE – Review of Puberty Blockers at 13. Similarly, in the review of cross-sex hormones, NICE concluded that the relevant studies were "uncontrolled observational studies, which are subject to bias and confounding and were of very low certainty using [a] modified GRADE" methodology. NICE – Review of Cross-Sex Hormones at 13.

3. The State of Florida. In 2022, researchers completed a systematic review at the request of the Florida Agency for Health Care Administration. *See* Romina Brignardello-Petersen & Wojtek Wiercioch, *Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence* 5 (May 16, 2022), https://perma.cc/S4A3-NKDY. They too found that the evidence supporting these interventions was weak. "Due to the important limitations in the body of evidence," they concluded, "there is great uncertainty about the effects of puberty blockers, cross-sex hormones, and surgeries in young people with gender dysphoria." *Id*.

4. Sweden. In 2023, Swedish researchers published a systematic review that was commissioned by Sweden's Agency for Health Technology and Assessment of Social

Services. *See* Jonas F. Ludvigsson, et al., *A Systematic Review of Hormone Treatment for Children with Gender Dysphoria and Recommendations for Research*, 112 ACTA PAEDIATRICA 2279 (2023), https://perma.cc/E7S9-7CLB. The review concluded that the "[e]vidence to assess the effects of hormone treatment" on (among other things) mental health in minors "with gender dysphoria is insufficient." *Id.* at 2280. Specifically, it noted that "[l]ong-term effects of hormone therapy on psychosocial health are unknown," and using puberty blockers to treat gender dysphoria "should be considered experimental treatment." *Id.*

5. The Cass Review Final Report. Most recently, researchers from York University published a series of systematic reviews as part of the Cass Review. The York University researchers conducted systematic reviews of the evidence for both puberty blockers and cross-sex hormones. *See* Jo Taylor et al., *Interventions To Suppress Puberty in Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review*, ARCHIVES DISEASE CHILDHOOD 1 (2024), https://perma.cc/UFL5-7RPB ("Taylor – Puberty Blockers"); Jo Taylor et al., *Masculinising and Feminising Hormone Interventions for Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review*, ARCHIVES DISEASE CHILDHOOD 1 (2024), https://perma.cc/ACK3-XB8D ("Taylor – Cross-Sex Hormones"). In their review of puberty blockers, the researchers determined that their "findings add to other systematic reviews in concluding there is insufficient and/or inconsistent evidence about the effects of puberty suppression on gender dysphoria, body satisfaction, psychological and psychosocial health, cognitive development, cardiometabolic risk and fertility." Taylor – Puberty Blockers at 12. Similarly, in their

review for cross-sex hormones, the researchers concluded that their "findings add to other systematic reviews in concluding there is insufficient and/or inconsistent evidence about the risks and benefits of hormone interventions in this population." Taylor – Cross-Sex Hormones at 6.

In sum, all these systematic reviews concluded the same thing: there is no reliable evidence to justify the use of puberty blockers and cross-sex hormones as a treatment for gender dysphoria in minors.

III. Appellants Either Misunderstand Or Misrepresent The Principles Of Evidence-Based Medicine.

Appellants have no answer to the systematic reviews described above. So instead, they try to change the subject. First, they point to various individual studies that, they say, show these interventions are safe and effective. But the systematic reviews above *already analyzed* those studies and concluded they did not provide reliable evidence. Next, they say that providing interventions based on low quality evidence is no big deal. For interventions with low risks, that may be true; for interventions that involve sterilization and stunting the brain development of minors, that is false. Finally, they attempt to conflate biology-denying interventions with the use of puberty blockers and surgical procedures to treat *other* conditions. But those other treatments carry risks and benefits that *vastly* differ from the treatments Missouri has banned for minors; Appellants' attempt to conflate them is meritless.

A. Appellants Rely On Evidence That Systematic Reviews Have Already Concluded Are Unreliable.

Appellants cite no systematic reviews in support of their argument—because there are none. Instead, they open with "clinical experience"—*i.e.*, the *lowest* form of medical evidence—and the very studies that numerous systematic reviews have concluded are subject to high risk of bias. Appellants' Opening Br. at 20 (July 8, 2025) ("Apellants' Br."). Based on recounted experiences of clinicians who happen to support the Appellants' policy preferences, Appellants would have this Court hold that Missouri has no lawful interest in regulating medicine to reflect evidence. Trust the anecdotes of individual clinicians over systematic reviews, the brief impliedly argues. *Id.* at 20, 23, 96. That approach is based on ideology, not evidence. *See supra* section I.

Appellants' brief also exemplifies why it is wrong to bypass systematic reviews for individual studies. Appellants scatter references to a purported "consensus (or at least, overwhelmingly majority view)" that these interventions are beneficial. *Id.* at 79; *accord id.* at 63, 99, 100-05. But the expert witnesses who claim consensus have relied on the very studies that systematic reviews have concluded are so weak they are unreliable. *See supra* section II; *see also* Evidence-Based Medicine User Guide at 23.

Appellants offer shrugging indifference that the evidence is either low or very low quality under GRADE. *See* Appellants' Br. at 33. They purport to warn the Court that "low" or "very low" doesn't really mean what it says. It is true that "low" or "very low" quality has a specialized meaning in the GRADE methodology. *Id.* at 87. But how that specialized meaning helps Appellants is a mystery. "Low" or "very low" quality evidence entails

"limited" or "very little" confidence that the results are accurate, and the truth "may be" or "is likely to be substantially different from" what the study says. Balshem, *supra*, at 404. To make the point tangible: If a doctor tells you that she has "limited" or "very little confidence" that a drug will work, you will not infer that the drug has been proven to be effective. Appellants ask you to trust the doctor anyway.

B. Appellants Conflate Medicalized Transitions With Interventions That Present Vastly Different Risks and Benefits.

Appellants argue "that it was 'very common' for clinical practice guidelines to make recommendations based on 'low' or 'very low' quality evidence." Appellants' Br. at 87. The argument is misleading at best. Appellants fail to explain two critical points: (1) the GRADE methodology sometimes requires a strong recommendation *against* the intervention in the face of low quality evidence; and (2) GRADE offers five paradigmatic situations where a strong recommendation can be made based on low-quality evidence—and none of them applies here.

As an initial matter, GRADE recommends a strong recommendation *against* an intervention based on low-quality evidence in four of the five paradigms—meaning the provider should *refuse* to offer the intervention that is supported by low-quality evidence. *See* Ming C. Chong et al., *Strong Recommendations from Low Certainty Evidence: A Cross-Sectional Analysis of a Suite of National Guidelines*, 23 BMC MED. RSCH. METHODOLOGY 1, 3 (2023). The only situation in which GRADE permits a strong recommendation *in favor* of an intervention based on low-quality evidence is when a patient is facing a "[l]ife-threatening (or catastrophical) situation." *Id.* The example

provided is when there is an "absence of effective alternatives" for a disease with a "high mortality" rate. *Id.* Gender dysphoria does not have a "high mortality" rate; as explained below, there is no reliable evidence suggesting that these interventions have any effect on suicide. And gender dysphoria can be treated through psychotherapy as health officials in Finland, Sweden, the U.K., and Norway all recommend. *See, e.g.*, Frieda Klotz, *A Teen Gender-Care Debate Is Spreading Across Europe*, THE ATLANTIC (Apr. 28, 2023), https://perma.cc/6M7F-3G8L; *accord United States v. Skrmetti*, 145 S. Ct. 1816, 1825 (2025).

By claiming some other field of medicine uses interventions backed by low-quality evidence, Appellants are comparing apples to oranges. The risks and benefits associated with different interventions for different conditions should not be conflated. *See* Evidence-Based Medicine User Guide at 6 (noting that providers must determine "the tradeoff among the benefits, risks, and burdens of alternative management strategies" (emphasis omitted)). It is common sense that uncertainty about the *benefit* of a drug is less significant when the *risks* associated with taking that drug are low. For example, if there is low *risk* in brushing one's teeth with fluoride, then one need not be concerned if there is low quality evidence of the *benefit* of brushing with fluoride toothpaste. Relatedly, it is common sense that uncertainty about the benefit of a drug is less significant when the *marginal* risk associated with taking that drug is low. For example, if there is little marginal risk in prescribing an experimental drug to a patient suffering from an aggressive form of life-threatening cancer, then uncertainty about the benefit is less concerning. This principle—close to a "nothing-to-lose" situation—is reflected in the lone situation where GRADE permits a strong

recommendation in favor of an intervention supported by low-quality evidence. *See* Chong, *supra*, at 3. The upshot is that using interventions to treat different conditions carries different risks and benefits that must be analyzed separately.

Appellants ignore this fundamental principle, as if the level of evidence that justifies fluoride in toothpaste also justifies surgically removing a child's body parts. They suggest that, since clinical guidelines on obesity, adrenal hyperplasia and CPR recommend medical treatments are based on low-quality evidence, then providers should also be permitted to offer biology-denying interventions based on low-quality evidence. *See* Appellants' Br. at 33.

The critical flaw in this argument is that Appellants' examples do not involve interventions that share a similar risk-benefit profile with the ones at issue here. Take puberty blockers as an example. They can be used to treat central precocious puberty or to treat gender dysphoria. When used for gender dysphoria, even those who recommend their use note that, "in the face of low-quality evidence," clinicians should "inform" patients of "options for fertility preservation." Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. CLINICAL ENDOCRINOLOGY & METABOLISM 3869, 3879 (2017). That recommendation follows from the reality that biology-denying interventions suppress a patient's natural puberty. A gender dysphoric child whose puberty is suppressed and then continues on to cross-sex hormones will be sterilized. The use of puberty blockers to treat central precocious puberty carries no similar risks. In addition, the effects of pubertal suppression on brain development are entirely unknown, and puberty blockers are

administered far later into adolescence when used to treat gender dysphoria than when used to treat central precocious puberty. *See* Cass Review, *supra*, at 178.

In sum, the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria carries a *host* of known harms and risks and has no reliable evidence of benefit. The treatments that Appellants attempt to analogize to biology-denying interventions at issue here have no comparable risk-benefit profile. Missouri is entirely justified in banning these dangerous and unproven interventions.

C. There Is No Reliable Evidence That Puberty Blockers And Cross-Sex Hormones Reduce The Risk Of Suicide.

Appellants warn of "danger," Appellants' Br. at 58, and imply that, absent reversal, children will die. *See id.* at 92-93, 105. This implication is irresponsible in light of the actual evidence on this question. As WPATH's own researcher admitted: "There is insufficient evidence to draw a conclusion about the effect of hormone therapy on death by suicide among transgender people." Kellan E. Baker et al., *Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review*, 5 J. ENDOCRINE SOC. 1, 13 tbl.6 (2021); *accord id.* at 12 ("It was impossible to draw conclusions about the effects of hormone therapy on death by suicide."). And in what is likely the most controlled environment that is currently feasible, a researcher in the U.K. concluded that there was no evidence of a rise in suicides after the country's health service had restricted the use of puberty blockers as a treatment for gender dysphoria. *See Puberty Blocker Curb Has Not Led to Suicide Rise—Review*, BBC (July 20, 2024), https://perma.cc/X6P5-EP8T.

As the trial court found, Appellants cite no evidence about suicide. D185 at 29; App. 1. And they present no new evidence here. Instead, they refer to evidence of suicidal ideation. *See* Appellants' Br. at 93. The distinction is important. "[T]he development of suicidal ideation and . . . suicide desire to attempts are distinct processes with distinct explanations." E. David Klonsky et al., *Ideation-to-Action Theories of Suicide: A Conceptual and Empirical Update*, 22 CURRENT OP. PSYCH. 38, 38 (2017). Systematic reviews reinforce the distinction. *See, e.g.*, Richard T. Liu et al., *Prevalence and Correlates of Suicide and Nonsuicidal Self-injury in Children: A Systematic Review and Meta-analysis*, 79 JAMA PSYCHIATRY 718, 722 (2022); J. John Mann et al., *Improving Suicide Prevention Through Evidence-Based Strategies: A Systematic Review*, 178 AM. J. PSYCHIATRY 611, 611 (2021). Thus, this Court should not assume that evidence-based medicine will lead to children's death. To the contrary, Missouri has done the right thing in ensuring that gender ideology is not allowed to displace the principles of evidence-based medicine when doctors treat vulnerable young people suffering from gender dysphoria.

CONCLUSION

For these reasons, this Court should affirm the decision below.

Dated: September 2, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE AND COMPLIANCE

The undersigned certifies that the foregoing document was filed with the Court's electronic filing system on September 2, 2025, which pursuant to Rule 43.01(c) will send notice to the attorneys of record for all parties, including requiring local counsel for the parties to transmit copies to out of state counsel.

Pursuant to Rule 84.06(c), the undersigned hereby certifies that: (1) this brief complies with and includes the information required by Rule 55.03; (2) this brief complies with the limitations contained in Rule 84.06(a) and (b); and (3) this brief contains 3,885 words as calculated by Microsoft Word software used to prepare this brief. Finally, the undersigned certifies that this electronically filed brief was scanned and found to be virus free.

Dated: September 2, 2025

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