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4/17/2023 Court of Appeals Division I State of Washington

## IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

TANESSA DESRANLEAU, individually and as the Personal Representative of the ESTATE of JAY'BREON DESRANLEAU,	No. 82213-6-I DIVISION ONE
Appellant,	PUBLISHED OPINION
٧.	
HYLAND'S, INC., STANDARD HOMEPATHIC LABORATORIES, INC., and STANDARD HOMEPATHIC COMPANY,	
Respondents,	
MICHELE REID,	
Defendant.	

CHUNG, J. — In 2014, 13-month-old Jay'Breon Bush Desranleau tragically died in his crib. In the days before his death, Jay'Breon<sup>1</sup> had a cold, and his caregiver gave him several medications, including "Hyland's Baby Tiny Cold Tablets," a homeopathic cold remedy manufactured by Hyland's, Inc. Jay'Breon's mother, Tanessa Desranleau, sued Hyland's, claiming that an ingredient in the cold tablets, *Gelsemium sempervirens* (GS), caused his death. Hyland's moved for summary judgment. Applying <u>Frye v. United States</u>, 293 F.

<sup>&</sup>lt;sup>1</sup> For clarity, we refer to Jay'Breon by his first name. We intend no disrespect.

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1013 (D.C. Cir. 1923), ER 702, and ER 703, the trial court excluded the opinion of Desranleau's expert, Dr. Marvin Pietruszka, who opined that the Hyland's tablets consumed by Jay'Breon more likely than not, and with a reasonable degree of medical certainty, caused his death. The court then dismissed Desranleau's lawsuit on summary judgment. Desranleau appeals. For the reasons below, we reverse and remand.

#### FACTS

On the morning of January 19, 2014, Michelle Reid found 13-month-old Jay'Breon lying on his stomach and unresponsive in his crib.<sup>2</sup> He had passed away.

Law enforcement officers and a medical examiner investigated the matter.

Reid had been taking care of Jay'Breon. She told the officers that, in the days

before his death, Jay'Breon had a cold. Reid treated the child with "Hyland's

Baby Tiny Cold Tablets," a homeopathic cold remedy manufactured by Hyland's,

Children's Tylenol, and Baby Vicks Vapor Rub.

The medical examiner who conducted the autopsy, Dr. Richard Harruff,

noted that Jay'Breon's lungs were congested. He determined,

The cause of death of this 13 month old male is not explained by postmortem examination. There are no natural disease or injuries detected that could have contributed to or caused death. However

<sup>&</sup>lt;sup>2</sup> Hyland's briefing on appeal discusses Jay'Breon's living conditions and caretaking, apparently seeking to cast them in a negative light. It claims it did so because this information was relevant to "whether there could be a cause of death that has not been ruled out." But the central issue in this appeal is whether the trial court properly excluded Dr. Pietruszka's opinion. Hyland's statements do not advance the analysis of that issue.

the circumstances surrounding death are not well explained. He was apparently found with his head covered by a comforter and blanket. Because external factors contributing to his death cannot be excluded, the cause and manner of death are classified [as] undetermined.

Jay'Breon's mother, Desranleau, sued Hyland's, asserting claims under the Washington Product Liability Act<sup>3</sup> (WPLA) and the Consumer Protection Act,<sup>4</sup> and requesting punitive damages under California law. Desranleau alleged that GS, a "medicinal herb" listed on the packaging as an ingredient in the cold tablets, caused Jay'Breon's death.<sup>5</sup>

## A. Prior summary judgment and appeal

Hyland's moved for summary judgment, arguing Desranleau provided no

admissible evidence that Hyland's Cold Tablets caused Jay'Breon's death. See

Desranleau v. Hyland's, Inc., 10 Wn. App. 2d 837, 841-42, 450 P.3d 1203

(2019). In response, Desranleau submitted an opinion from Dr. Pietruszka, who declared, "Based upon the available information, I have been able to determine, more likely than not and with a reasonable degree of medical certainty, that the ingredients in the Hyland's product that were consumed by Jay'Breon caused his untimely death." The trial court did not rule on the admissibility of Dr. Pietruszka's

opinion. <u>Id.</u> at 846.

<sup>&</sup>lt;sup>3</sup> Ch. 7.72 RCW.

<sup>&</sup>lt;sup>4</sup> Ch. 19.86 RCW.

<sup>&</sup>lt;sup>5</sup> The background facts are more fully set out in this court's prior opinion upon review of the trial court's previous summary judgment dismissal of Desranleau's claims. <u>See Desranleau v. Hyland's, Inc.</u>, 10 Wn. App. 2d 837, 839-42, 450 P.3d 1203 (2019).

Desranleau also submitted Reid's statements to responding law enforcement officers that she gave Jay'Breon the cold tablets. <u>Id.</u> at 843. The trial court excluded Reid's statements as hearsay. <u>Id.</u> at 843. Concluding that there was no admissible evidence that Jay'Breon ingested the Hyland's tablets, the trial court dismissed the claims on summary judgment. <u>Id.</u> at 842, 846. Desranleau appealed. <u>Id.</u> at 842.

On appeal, we agreed that Reid's statements to the officers about administering cold tablets were inadmissible. <u>Id.</u> at 845. But we concluded that, after viewing all reasonable inferences—Jay'Breon's cold, Dr. Harruff's report describing Jay'Breon's lung congestion, and the medication recovered from the scene by responding law enforcement officers—a material question of fact existed as to whether Jay'Breon ingested the cold tablets. <u>Id.</u> at 845. We also concluded that we should not disregard Dr. Pietruszka's then opinions based on the arguments presented by Hyland's at that stage. <u>Id.</u> at 846-47. We thus reversed the dismissal of Desranleau's claims under the WPLA and affirmed the summary dismissal of her other claims. <u>Id.</u> at 849.

#### B. Expert testimony after remand

On remand, Hyland's deposed Dr. Pietruszka. He testified that he is a pathologist, and in this case, his focus was to use his knowledge of toxicology to help explain Jay'Breon's death. He identified three main topics that his opinions addressed: toxicity of GS, a differential diagnosis of the cause of death, and analysis of the "Bradford Hill" criteria to determine cause of death.

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#### 1. Toxicity of GS

Pietruszka testified that "[GS] is a toxic chemical. It's identified as a poison." Therefore, "this chemical substance should not have been incorporated into a homeopathic medication that is prescribed to anyone, but most certainly to infants." He said that "nanoparticles of [GS]" contain strychnine-type chemicals and injure cell function, and "even minute quantities [of GS] would have been potentially fatal." He acknowledged, "There are very few research studies that exist for herbal medicines, especially [GS] because it's a toxic substance, and especially studies that involve humans don't exist." Thus, Dr. Pietruszka stated, "I don't think anyone actually knows what the toxic and lethal dose is of [GS]."

Despite the lack of available information about a dose response, asked about whether any literature provide a specific unit of measurement at which GS becomes lethal, Dr. Pietruszka said "[t]hose measurements play no role in this case." Instead, he relied on "the relationship between the science that we know about [GS], its relationship to strychnine, and its effect on the nervous system from the literature" to "explain what happened to this child." The literature "confirms the direct toxicity of [GS] on the central nervous system. . . . Even small doses can affect respiration. Larger doses can cause paralysis of the respiratory center." Dr. Pietruszka relied on articles that stated that "nanoparticle toxicity occurs . . . in [GS] administration and [GS] actually can affect the internal organelles of the cell and thereby cause toxicity." He testified, "[W]hen you put a

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tablet [containing GS] in the mouth, it can readily pass through cell membranes

and go right to the brain, which is probably 80-90 percent lipid, fat."

Dr. Pietruszka also explained,

However, more recently, with a greater understanding of the effects of nanoparticles on the human body and the use of nanoparticles in various treatments, it becomes clear that homoeopathy [sic], the concept of homeopathy and the mechanism by which homeopathy works, deals essentially with the ability of nanoparticles, very small particles of, in this case, a toxic substance to enter into the system and to affect an adverse occurrence on cell structures—on cell structures.

So in this case what my understanding is—if I want to get to the real basic what happened, is you have—an infant is administered at least eight tablets a day of [GS], [GS] contained within tablets. The exact concentration of that [GS] is not known. There is some concern about the manufacturing process. We don't know if the chemicals in those tablets are evenly distributed through all the tablets or whether some have higher concentration than others.

Nevertheless, even small concentrations of [GS] are described in the literature as potentially toxic.

In Dr. Pietruszka's opinion, "In reviewing the literature, [GS is] not

recommended for use, or if it is recommended to be used, it is recommended to

be used with extreme caution." He referenced medical articles that advised not to

give GS to children, as "[i]t could poison them, even a very small amount." In his

opinion, GS "should not have been incorporated into a homeopathic medication

that is prescribed to anyone, but most certainly to infants."

# 2. Differential diagnosis of cause of death

Dr. Pietruszka testified that he "performed an extensive differential

diagnosis of cause of death." He stated,

I have reviewed the autopsy [and] I did not find any aspects of the autopsy to identify any medical condition that could have caused this baby's death. I believe that the biochemical nature of [GS] in the setting in which it has been dispensed can readily explain how and why this baby died when he died.

Based on his review of Jay'Breon's autopsy report and toxicological literature, and using the differential diagnosis method of ruling out other possible causes of death, he opined, "[T]here are no inherent medical conditions that would have caused this child to die suddenly."

Dr. Pietruszka characterized the case as one of "toxic encephalopathy. This baby suffered direct toxicity to the human brain, causing death. . . . [T]his is the effect of the neurotoxin." The pathologist who conducted the autopsy observed cerebral edema, which Dr. Pietruszka stated was "one of the findings that you find in toxic encephalopathy." He also opined that "because the drug is so toxic, because the therapeutic window is so narrow, which means that the margin between therapeutic efficacy and toxicity is so small that death can occur immediately . . . [and t]here's not even enough time for very many changes to be visualized, to be identified."

Dr. Pietruszka determined other possible causes of death could be ruled out. The child did not die of deprivation of oxygen because hypoxia causes red neurons, and red neurons were not observed. He ruled out suffocation by blankets because it occurs more commonly in younger infants who "are placed in one position and don't move very far," whereas infants of 13 months of age can change their position. Also, children who suffer from asphyxia frequently have

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petechial hemorrhages and abrasions of the nose that Jay'Breon did not have. Ultimately, after reviewing the autopsy report and based on his experience as a clinician and pathologist, Dr. Pietruszka stated,

I can't find anything else . . . no suffocation, no entrapment, no infection, no other metabolic disease. They checked every metabolic disease they can think of. There's nothing going on with the heart. There's nothing going on with the intestines.

Thus, he concluded that there was nothing in that autopsy to explain the cause of death "except for the administration of a toxic chemical . . . that get[s] absorbed right away, and it is the [sic] going to the base of the brain."

Further, even though it had been approximately nine hours from the last administration of the Hyland's tablet and when Jay'Breon was found deceased, "the repeated administration of a toxic drug that has a predilection for fatty tissue to me suggests that [the drug] would be there for a prolonged period of time." Although Dr. Pietruszka said he did not know the amount of GS Jay'Breon ingested, or the amount of GS necessary to be lethal, he testified, "[W]e don't have any other reasonable cause of death."

#### 3. <u>Analysis of Bradford Hill criteria for causation of death</u>

Dr. Pietruszka applied the Bradford Hill criteria for causation, a "methodology of determining causation . . . characteristically used in medical cases" that involves analyzing nine criteria. Dr. Pietruszka testified that the Bradford Hill analysis was generally accepted in the medical field and described his analysis of each of these criteria.

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As to the first criterion, he concluded the strength of association of GS to causing a toxic effect, based on literature, was a strong association. Regarding the second criterion, dose response, his opinion was a strong dose was not needed, and "even a dose in the nano level can be significant." As to the third criterion, consistency of findings by different researchers, he found that the literature was consistent that GS is a poison.

Dr. Pietruszka also analyzed the fourth criterion, determining there was biological plausibility, and the fifth criterion, temporal causation, a direct association between the time of administration of the toxic substance and the death. On the sixth criterion, whether he controlled for confounding factors or bias, Dr. Pietruszka determined the autopsy helped eliminate other reasonable causes of sudden death.

As to specificity, the seventh criterion, he opined that the exposure caused specific results, that the baby stopped breathing, in line with the symptoms of GS poisoning. He determined that the eighth criteria, coherence, was also satisfied. Finally, as to the ninth criteria, analogy, Dr. Pietruszka looked to another Hyland's product, a teething drug that contained belladonna that caused death of babies, as well as COVID infection that "gets into the nose" and "causes brain symptoms, and it affects the nervous system."

Dr. Pietruszka noted that while one or two points could be argued, the Bradford Hill did not require all nine criteria; a majority was sufficient to establish causation. Applying this methodology, Dr. Pietruszka concluded to a reasonable

degree of medical certainty that causation for the death was "the administration of [GS]."

C. <u>Trial court's ruling on Hyland's motion to exclude Dr. Pietruszka and</u> <u>motion for summary judgment</u>

Hyland's moved to exclude Dr. Pietruszka as an expert witness on two

separate grounds: (1) his opinions "violate Frye as unreliable and not generally

accepted in the medical community," and (2) his opinions "lack foundation, are

speculative, and rely on baseless assumptions, rendering them unhelpful" under

ER 702 and ER 703. Hyland's also moved for summary judgment dismissal of

Desranleau's WPLA claim.

. . .

The trial court delivered an oral ruling at the hearing. It explained,

[T]here's certainly evidence in the record from which an inference could be drawn that [GS] is present. It's listed as an ingredient on the product sol[d]. However, that information may be rebutted by the hard data referred to in Dr. Phil[I]ip's<sup>[6]</sup> declaration testimony of April 2018.

And—but I don't need to reach that, I think, here. The—the evidence clearly established—and I don't think there's any dispute—

Accordingly, the level at which [GS] is included in Hyland's Tiny Cold Tablets is 0.0015 ppm to 0.0080 ppm, or 1.5 ppb to 8 ppb. To be clear, this is an extraordinarily miniscule amount. At this level of dilution, strychnine (which is a highly toxic alkaloid) would not be harmful. Further yet, at this level of dilution, no one would even experience symptoms of exposure to strychnine. Additionally, testing performed by Hyland's on finished Tiny Cold Tablets demonstrates that [GS] could not even be detected at 8 parts per billion (ppb). . . . Thus, after the product has been completed, [GS] cannot even be detected in Hyland's Tiny Cold Tablets.

<sup>&</sup>lt;sup>6</sup> Defense expert Dr. Scott Phillips declared,

<sup>[</sup>GS] is included in Hyland's Tiny Cold Tablets at 6X. This means that the tincture from which the [GS] is incorporated into Tiny Cold Tablets goes through [six] dilution steps prior to being incorporated into Hyland's Tiny Cold Tablets.

that, if it is present, it's present at undetectable levels. And there is no support part [sic] scientific theory that a—that GS present at undetectable levels could be lethal.

The trial court excluded Dr. Pietruszka's opinion under <u>Frye</u>, determining it was not based on "science but on supposition and speculation." In its oral ruling, the

trial court also excluded Dr. Pietruszka's opinion under ER 702 because it lacked

foundation. It said that Dr. Pietruszka is "not able to cite to any other expert or

any published, peer-reviewed study or even—even a comparable compound that

would support his theory here." In its written ruling, the trial court stated,

"Dr. Pietruszka's opinions fail to satisfy the requirements of ER 702 and ER 703."

As a result, determining that there was no evidence of causation, the trial court

dismissed the WPLA claim on summary judgment. Desranleau filed a motion for

reconsideration,<sup>7</sup> which the court denied.

Because the level at which [GS] is included in Hyland's Tiny Cold Tablets is so miniscule, substantial variations in that level, even assuming there is any variation, could not realistically result in any risk of harm.

<sup>&</sup>lt;sup>7</sup> Along with the motion for reconsideration, Desranleau submitted approximately 400 pages of documents for the first time, which the trial court declined to consider. Desranleau also included an appendix to her opening brief on appeal, which includes some of the same articles about GS and GS poisoning submitted below on reconsideration. Hyland's contends, and Desranleau does not dispute, that we should not consider the appendix. We agree. "On review of an order granting or denying a motion for summary judgment the appellate court will consider only evidence and issues called to the attention of the trial court." RAP 9.12. We consider only the appendices that were in the record and available to the trial court before Desranleau's motion for reconsideration. And because Desranleau presents no argument on the order denying reconsideration, we do not review that decision.

Desranleau appeals the trial court's orders excluding Dr. Pietruszka as an

expert, granting summary judgment, denying reconsideration,<sup>8</sup> and denying

sanctions against counsel for Hyland's.9

# ANALYSIS

Desranleau contends the trial court erred in excluding Dr. Pietruszka's

opinion and in granting Hyland's summary judgment motion.<sup>10</sup> We address each

argument in turn.

# I. Exclusion of Dr. Pietruszka's Opinion

In Washington, expert testimony must satisfy Frye and ER 702. Lakey v.

Puget Sound Energy, Inc., 176 Wn.2d 909, 918, 296 P.3d 860 (2013). "Frye and

<sup>&</sup>lt;sup>8</sup> Desranleau filed a supplemental notice of appeal, appealing the order denying reconsideration. But on appeal, she offers no argument on the issue. Thus, we do not address the claim. <u>See Prostov v. Dep't of Licensing</u>, 186 Wn. App. 795, 823, 349 P.3d 874 (2015) ("A party abandons assignments of error unsupported by argument and will not be considered on appeal.").

<sup>&</sup>lt;sup>9</sup> After Desranleau moved for reconsideration, Hyland's moved for CR 11 sanctions against Desranleau's counsel. Then, Desranleau moved for CR 11 sanctions against counsel for Hyland's, which the trial court denied. The record does not include the trial court's ruling on the CR 11 motion against Desranleau's counsel, which is not at issue here.

In a supplemental notice of appeal, Desranleau appeals the trial court's denial of her motion for CR 11 sanctions against counsel for Hyland's. However, because she does not assign error to the trial court's ruling and does not support her argument for sanctions with citation to legal authority, we do not consider it. RAP 10.3(g) ("The appellate court will only review a claimed error which is included in an assignment of error or clearly disclosed in the associated issue pertaining thereto."); RAP 10.3(a)(6); <u>Norcon Builders, LLC v. GMP Homes VG, LLC</u>, 161 Wn. App. 474, 486, 254 P.3d 835 (2011) (holding that appellate courts will not consider arguments unsupported by authority).

Also, on appeal, Desranleau "preemptively moves for sanctions under [CR] 11" for any improper conduct on appeal. But she does not support her argument with citation to legal authority showing that this court may provide such relief, so we do not consider it. <u>See</u> RAP 10.3(a)(6); <u>Norcon Builders, LLC</u>, 161 Wn. App. at 486.

ER 702 work together to regulate expert testimony: <u>Frye</u> excludes testimony based on novel scientific methodology until a scientific consensus decides the methodology is reliable; ER 702 excludes testimony when the expert fails to adhere to that reliable methodology." <u>Id.</u> at 918-19.

While we typically review decisions to exclude expert testimony for abuse of discretion, we review de novo a trial court's evidentiary ruling made in conjunction with a summary judgment ruling.<sup>11</sup> Frausto v. Yakima HMA, LLC, 188 Wn.2d 227, 231, 393 P.3d 776 (2017) (de novo standard applies to evidentiary ruling made in conjunction with summary judgment motions); Watness v. Seattle, 16 Wn. App. 2d 297, 305, 481 P.3d 570 (2021) (same). We also review a trial court's Frye ruling de novo. Id. at 305. "Our de novo review of admissibility of scientific theory or methodology under Frye need not be confined to the record and may involve consideration of the available scientific literature, secondary legal authority, and cases in other jurisdictions." Ruff v. Dep't of Labor & Indus., 107 Wn. App. 289, 300, 28 P.3d 1 (2001), overruled on other grounds by Anderson v. Akzo Nobel Coatings, Inc., 172 Wn.2d 593, 260 P.3d 857 (2011); see also State v. Copeland, 130 Wn.2d 244, 255-56, 922 P.2d 1304 (1996)

<sup>&</sup>lt;sup>11</sup> Hyland's attempts to draw a distinction based on the fact that in the cases Desranleau cited, the court was asked to strike parts of a declaration submitted in summary judgment proceedings, whereas here, Hyland's filed a motion to exclude an expert witness. This is a distinction without significance when, as here, the evidence is being considered for summary judgment purposes. <u>See, e.g.</u>, <u>Anderson v. Akzo Nobel</u> <u>Coatings, Inc.</u>, 172 Wn.2d 592, 600, 260 P.3d 857 (2011) (applying de novo standard to review grant of motion in limine to strike experts and grant of summary judgment).

(review may extend beyond record, noting impracticality of true cross-section of scientists testifying at a hearing).

1. Frye analysis

A <u>Frye</u> analysis seeks to determine "whether the evidence offered is based on established scientific methodology." <u>Anderson</u>, 172 Wn.2d at 603 (quoting <u>State v. Gregory</u>, 158 Wn.2d 759, 829, 147 P.3d 1201 (2006)). The <u>Frye</u> test is implicated only where the opinion offered is based on novel science. <u>Anderson</u>, 172 Wn.2d at 611. In making a <u>Frye</u> determination, the trial court considers "(1) whether the underlying theory is generally accepted in the scientific community and (2) whether there are techniques, experiments, or studies utilizing that theory which are capable of producing reliable results and are generally accepted in the scientific community." <u>Id.</u> (quoting <u>State v. Riker</u>, 123 Wn.2d 351, 359, 869 P.2d 43 (1994)).

However, the *Frye* rule should not be confused with the "reasonably relied upon" language in Rule 703:

The *Frye* rule relates to the expert's scientific principles and techniques. By contrast, Rule 703 relates to the factual information relied upon by the expert, i.e., to the factual basis for the expert's opinion.

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§ 702.19, at 84 (6th ed. 2016).

Desranleau contends the trial court should not have conducted a Frye

analysis because the theory of GS toxicity is not novel, citing Anderson. Id. at

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612 ("The <u>Frye</u> test is implicated only where the opinion offered is based upon novel science."). In the alternative, Desranleau asserts that if the trial court did not err by conducting a <u>Frye</u> analysis, its inquiry should have focused on the second prong, whether Dr. Pietruszka's testimony adhered to an accepted methodology, rather than on his causation theory. Because the trial court determined that the scientific community does not generally accept Dr. Pietruszka's theory, it did not address the second prong of the <u>Frye</u> analysis.

Hyland's argues that the trial court properly excluded Dr. Pietruszka's testimony under <u>Frye</u> because "Dr. Pietruszka's causation theory fails both steps of the <u>Frye</u> analysis." Specifically, Hyland's challenges Dr. Pietruszka's "causation theory" for failing to provide analysis regarding Jay'Breon's metabolism, weight, or dose, or any form of quantitative analysis; the level of GS in Hyland's products; and because "he is unaware of chemicals that are lethal in undetectable nanoparticles." Thus, Hyland's argues, because so little is known about GS and its toxicity, under the second component of the <u>Frye</u> test, no testing or analysis could possibly disprove the causation theory, so the opinion should be excluded on that basis as well.

We agree with Desranleau that exclusion of Dr. Pietruszka's testimony under <u>Frye</u> was error. As the Supreme Court in <u>Anderson</u> held, "This court has consistently found that if the science and methods are widely accepted in the relevant scientific community, the evidence is admissible under <u>Frye</u>, without separately requiring widespread acceptance of the plaintiff's theory of causation."

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172 Wn.2d at 609. Moreover, "[a]n expert opinion regarding application of an accepted theory or methodology to a particular medical condition does not implicate <u>Frye</u>."<sup>12</sup> <u>Reese v. Stroh</u>, 128 Wn.2d 300, 307, 907 P.2d 282 (1995). These principles apply to the situation here.

As described above, Dr. Pietruszka's theory of causation rested on three opinions, including that based on his review of the scientific literature, GS is toxic. Rather than contest this basic premise, Hyland's suggests that there had to be generally accepted theories as to what was a lethal dose of GS before Dr. Pietruszka could opine on causation. Hyland's complains that Dr. Pietruszka did not calculate, test, or cite studies testing the lethality of undetectable quantities of GS. But as Dr. Pietruszka explained, there are no studies regarding specific doses that are lethal for humans because GS is a toxic substance. Dr. Pietruszka also testified that no test could accurately quantify how much GS would be lethal, so testing Jay'Breon's tissue postmortem for GS would provide inaccurate information.

The Supreme Court rejected reasoning similar to that of Hyland's in <u>Reese</u> <u>v. Stroh</u>, 128 Wn.2d 300. There, plaintiff had a condition, AAT deficiency, for which the FDA had approved therapy using a drug called Prolastin. <u>Id.</u> at 302-03. The plaintiff filed suit against his doctor, claiming his failure to prescribe Prolastin

<sup>&</sup>lt;sup>12</sup> "A *Frye* objection goes to the expert's underlying theory and methods of analysis, *not to the conclusion reached* by the expert. The issue is whether the expert's methodology is generally accepted as being *capable* of producing an accurate result, not whether the expert employed the methodology correctly." 5B TEGLAND, <u>supra</u>, § 702.19, at 84.

resulted in worsening lung function. <u>Id.</u> at 303. Plaintiff's expert opined that Prolastin therapy would have been effective for the plaintiff, but the trial court excluded the opinion because there had been no statistically significant studies proving the efficacy of this therapy for AAT deficiency. <u>Id.</u> at 304-05. The <u>Reese</u> court held the trial court's exclusion of the expert opinion under <u>Frye</u> was improper because the uncontroverted testimony was that the FDA approved the use for this condition. <u>Id.</u> at 307. <u>Frye</u> was not implicated; rather, the court assessed the admissibility of the causation opinion under ER 702 and 703's general reliability standards. <u>Id.</u> at 308.

Similarly, here, as with the theory that Prolastin could be prescribed for AAT deficiency, Hyland's does not dispute the basic theory that GS is toxic. Dr. Pietruszka's opinion in that regard does not require a <u>Frye</u> analysis. "The reasonableness of the factual basis for an expert's opinion is governed by Rule 703," not <u>Frye</u>. 5B TEGLAND, <u>supra</u>, § 702.24, at 110.

Further, Dr. Pietruszka reached his opinion on causation by applying widely used methodologies for determining medical causation, the process of differential diagnosis and consideration of Bradford Hill criteria. "Many medical opinions on causation are based upon differential diagnoses." <u>Anderson</u>, 172 Wn.2d at 610; <u>see also In re Morris</u>, 189 Wn. App. 484, 494-95, 355 P.3d 355 (2015) (the differential diagnosis methodology is a "well-recognized and reliable" methodology for ascertaining causation and satisfies the <u>Frye</u> standard). A physician "may base a conclusion about causation through a process of ruling

out potential causes with due consideration to temporal factors, such as events and the onset of symptoms." <u>Id.</u>

Further, Dr. Pietruszka's opinion that ingesting a substance known to be toxic caused death is an opinion about causation, which, <u>Anderson</u> instructs, is not the proper focus for a <u>Frye</u> analysis. <u>See Anderson</u>, 172 Wn.2d at 609. Nor will we deem every subset of information on which a causation opinion is based, such as at what dose GS is lethal, to be a separate "theory" requiring general acceptance.<sup>13</sup> The <u>Anderson</u> court rejected this type of "ever more nuanced argument" that to satisfy <u>Frye</u>, there must be "general acceptance" as to "each discrete and ever more specific part of an expert opinion." <u>Id.</u> at 611. Otherwise, the court reasoned, "virtually all opinions based upon scientific data could be argued to be within some part of the scientific twilight zone." <u>Id.</u>

We thus hold that Dr. Pietruszka's opinion as to causation does not implicate the <u>Frye</u> test. The issues here are "fully resolvable" under the evidence rules, without <u>Frye</u>. <u>See Reese</u>, 128 Wn.2d at 308; <u>Anderson</u>, 172 Wn.2d at 611 (<u>Frye</u> is implicated only where the opinion offered is based upon novel science).

<sup>&</sup>lt;sup>13</sup> To the extent Hyland's relies on its expert Carl Wigren's opinion that Dr. Pietruszka could not have relied on "standard autopsy methodology" because Dr. Pietruszka himself did not perform an autopsy, this argument also does not counsel that Dr. Pietruszka's opinion should be subject to a <u>Frye</u> analysis. More properly, this concern is analyzed under ER 703, which allows experts to base their opinion testimony on facts or data, even if otherwise inadmissible, if "of a type reasonably relied on by experts in the field." We determine that it was proper under ER 703 for Dr. Pietruszka to rely on the medical examiner's autopsy report as it is a type of information reasonably relied upon by medical experts opining on causation. <u>See, e.g., State v. Lui</u>, 153 Wn. App. 304, 320-21, 221 P.3d 948 (2009) (in analysis of confrontation clause challenge, noting that expert witness properly applied his own expertise after review of autopsy report by another).

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## 2. <u>ER 702</u>

Even if evidence does not require a <u>Frye</u> analysis, "[o]f course the evidence must also meet the other evidentiary requirements of competency, relevancy, reliability, helpfulness, and probability." <u>Anderson</u>, 172 Wn.2d at 609. Desranleau argues the court erred in excluding the expert testimony and "commingled" the <u>Frye</u> and ER 702 analyses.<sup>14</sup> Hyland's contends the trial court properly excluded Dr. Pietruszka's testimony because he relied only on the "possibility of stratification coupled with the potential for [GS] to be toxic in high doses," based on this court's prior opinion in this case.<sup>15</sup> Also, Hyland's contends that Dr. Pietruszka did not know either the specific dose of GS that Jay'Breon was exposed to, nor the amount of GS in Hyland's Tablets. On de novo review, we hold that Dr. Pietruszka's testimony should not have been excluded, as it is based on facts, not speculation, and will assist the trier of fact.<sup>16</sup>

ER 702 provides, "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in

<sup>&</sup>lt;sup>14</sup> We note that the trial court in fact did explain, "Dr. Pietruszka's opinions lack foundation, are unreliable, and would invite the jury to engage in speculation. Accordingly, Dr. Pietruszka's opinions fail to satisfy the requirements of ER 702 and ER 703," and incorporated by reference its oral ruling that further explained its reasoning. Meanwhile, even as it complains about the trial court's deficiencies, Desranleau's own briefing commingles arguments and provides very little specific argument on ER 702 and none on ER 703. Because we review the trial court's ruling de novo, its brevity is of no moment. On the other hand, inadequate briefing to this court does a disservice to the client, as the court may decline to consider a party's arguments as a result.

<sup>&</sup>lt;sup>15</sup> Br. of Resp't at 27-28 (citing <u>Desranleau</u>, 10 Wn. App. 2d at 841).

<sup>&</sup>lt;sup>16</sup> Although the court below excluded the expert in part based on ER 703, Desranleau's briefing on appeal includes no separate ER 703 argument, and Hyland's argument is limited to a reference in a single footnote. Br. of Resp't at 46 n.14. Ordinarily, "[p]assing treatment of an issue or lack of reasoned argument is insufficient to

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issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." In assessing whether expert testimony would assist the trier of fact, the court should consider "whether the matter about which the expert would testify is beyond common knowledge and understanding." 5B TEGLAND, <u>supra</u>, § 702.15, at 69-70. Further,

The general rule bars testimony only on the aspects of a given subject that are matters of common understanding and knowledge. The expert is, of course, allowed to testify as to aspects of the subject that are *beyond* common understanding and knowledge.

Id. § 702.16, at 73. "It has been observed that the court 'will interpret possible

helpfulness to the trier of fact broadly and will favor admissibility in doubtful

cases.' " Id. § 702.15, at 70 (citation omitted).

To assist the trier of fact, "[t]he expert's opinion must be based on fact and cannot simply be a conclusion or based on an assumption." <u>Coogan v. Borg-</u> <u>Warner Morse Tec Inc.</u>, 197 Wn.2d 790, 801-02, 490 P.3d 200 (2021) (citations omitted). When Washington courts have refused to admit expert testimony as speculative, admission hinged on the expert's *basis* for forming the opinion, not on the expert's *conclusions*. <u>Volk v. DeMeerleer</u>, 187 Wn.2d 241, 277, 386 P.3d 254 (2016).

merit judicial consideration." <u>Palmer v. Jensen</u>, 81 Wn. App. 148, 153, 913 P.2d 413 (1996). However, as Desranleau generally challenged the ruling excluding Dr. Pietruszka, and the ruling relied on ER 703, we determine that the FDA letters and the information, including cited literature, in the letter from Wilfred Stock, Ph.D., are of a type reasonably relied upon by experts. Thus, under ER 703, Dr. Pietruszka's opinion could properly rely on them regardless of whether the information is admissible.

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Regarding medical causation, "[e]xpert medical testimony must meet the standard of reasonable medical certainty or reasonable medical probability." Anderson v. Akzo Nobel Coatings, Inc., 172 Wn.2d 593, 606–07, 260 P.3d 857 (2011). Such evidence "must rise above speculation, conjecture, or mere possibility." Reese, 128 Wn. 2d at 309. If a medical expert opines that "[a] causal relationship is probable or more likely than not, the quality of the evidence rises above speculation and conjecture and may be considered by the trier of fact." Merriman v. Toothaker, 9 Wn. App. 810, 815, 515 P.2d 509 (1973). See, e.g., Carlton v. Vancouver Care LLC, 155 Wn. App. 151, 168-69, 231 P.3d 1241 (2010) (rejecting challenge to rape trauma syndrome diagnosis testimony as not helpful to the jury because it lacked "precision" as to impact of rape on victim; experts "may express opinions if they can do so with reasonable medical certainty").

Here, Dr. Pietruszka determined "more likely than not and with a reasonable degree of medical certainty, that the ingredients in the Hyland's product that were consumed by Jay'Breon caused his untimely death." An expert is "allowed to testify as to aspects of [a] subject that are *beyond* common understanding and knowledge." 5B TEGLAND, <u>supra</u>, § 702.16, at 73. Expert opinion on cause of death falls within this ambit. <u>Id.</u> § 702.17, at 74.

Dr. Pietruszka provided the factual basis for his opinions both in his initial declarations and in his deposition testimony. Specifically, he said he did not know the level of GS in the cold tablets because the Hyland's manufacturing process

causes a "potential for stratification" of certain chemicals, and " 'stratification' can result in the tablets within the same product package as having varying levels of alkaloids." In support, Dr. Pietruszka cited to publicly available information that Hyland's production process for its Teething Tablets was faulty and resulted in some tablets with unacceptably high levels of a toxic substance, belladonna,<sup>17</sup> as well as to deposition testimony of a Hyland's employee, Eric Baier, that the company uses the same problematic production process both for the teething tablets and the cold tablets given to Jay'Breon. Despite not knowing the specific dose Jay'Breon consumed, Dr. Pietruszka provided the factual basis for his opinion that a toxic amount of GS in Hyland's cold tablets caused Jay'Breon's death.

Because Dr. Pietruszka testified that he did not know whether stratification actually occurred in the manufacturing of the cold tablets, Hyland's claims that his opinion lacks a factual basis that stratification resulted in a toxic amount of GS in the cold tablets. Hyland's states that to the contrary, the amount of GS in the tablets is "undetectable," and/or is a safe amount.<sup>18</sup>

<sup>&</sup>lt;sup>17</sup> Stratification occurs during manufacturing when an ingredient is not evenly distributed throughout a batch of the product. In 2012, the U.S. Food and Drug Administration (FDA) wrote to Hyland's expressing concern about the stratification of belladonna in manufacturing its teething tablets, and generally expressed concern about the manufacturing process for Hyland's products that include potentially toxic compounds like GS. In 2016, the FDA inspected Hyland's facility and found inconsistent levels of belladonna in the teething tablets.

<sup>&</sup>lt;sup>18</sup> Hyland's also challenges the factual basis for Dr. Pietruszka's statement that "there is no specific quantity of [GS] that is considered safe," for which he cited the October 2017 "Risk Calculation for Gelsemium sempervirens" by Dr. Wilfried Stock, Chairman of Homeopathic Pharmacopeia of the United States' (HPUS) Toxicological & Safety Committee. The article states that HPUS requires over the counter (OTC)

The case <u>Reese v. Stroh</u> is instructive on the topic of when a party claims a lack of particular factual basis equates to speculation. In <u>Reese</u>, as discussed above, the plaintiff's medical expert opined, to a reasonable degree of medical certainty, that therapy with the drug Prolastin would have been effective for the patient's condition. <u>Id.</u> at 304. The defendant objected because there had been no statistically significant studies proving the efficacy of the drug for this condition. <u>Id.</u> at 307. The court held, that while an expert could rely on statistics, such support was required "neither by ER 702, ER 703, nor by our case law." <u>Id.</u> at 309. Jurors could "certainly evaluate the foundation" for the expert's opinion, which was "based on the information known to the medical profession at the time of Plaintiff's treatment," and jurors also were "perfectly capable of determining what weight to give this kind of expert testimony." <u>Id.</u>

Similarly, here, the lack of information about the particular dose or dose response of GS does not render Dr. Pietruszka's opinion on causation speculative, particularly when he presents a plausible reason why dose response information does not exist. As Dr. Pietruszka explained, "it's a toxic substance, and especially studies that involve humans don't exist." "Even when gaps exist in the underlying data or research, expert testimony remains admissible if there is enough data for the expert to make a valid deduction and reach the conclusion they present to the jury." ROBERT H. ARONSON, THE LAW OF EVIDENCE IN

medications for the average adult human to have a GS potency of "3X," which means it has been diluted three times, while another organization requires it to have a potency of "4X." For a 10 kg child, Dr. Stock said the OTC potency level should be "5X."

WASHINGTON § 8.03[5][b], at 8-24 (5th ed. 2021) (discussing <u>L.M. v. ex rel.</u> <u>Dussault v. Hamilton</u>, 193 Wn.2d 113, 436 P.3d 803 (2019) (in case involving injuries to a newborn during birth, expert was allowed to testify about the "natural forces of labor" and whether they could have caused the injury even absent research on the subject)).

Rather than dose response, Dr. Pietruszka based his opinion on an article about medical treatments using certain nanoparticles to alter vital cell structures and on articles that say GS "is a known toxin." His opinion also was based on the fact that the label on the cold tablets' bottle identifies GS as an "active" ingredient.<sup>19</sup> Dr. Pietruszka is entitled to formulate his opinion even absent specific evidence of the quantity of GS Jay'Breon ingested. Jurors then may evaluate the foundation for the opinion on causation and determine the weight to give the testimony.

The situation here, where there are no studies establishing at what dose GS is lethal, is different from one in which there is information that an expert could have obtained or relied on, but did not. For example, in <u>Miller v. Likins</u>, an expert accident reconstructionist based his testimony about where an accident occurred "solely on [a witness's] declaration."<sup>20</sup> 109 Wn. App. 140, 149, 34 P.3d

<sup>&</sup>lt;sup>19</sup> The label constitutes an admission of a party-opponent, not hearsay. Regardless, "ER 703 allows an expert witness to base their opinion on facts or data regardless of their admissibility." <u>Desranleau</u>, 10 Wn. App. 2d at 844.

<sup>&</sup>lt;sup>20</sup> In <u>Miller</u>, this court reviewed the trial court's evidentiary ruling for abuse of discretion. 109 Wn. App. at 147, 150. As discussed above, we review de novo a trial court's evidentiary ruling made in conjunction with a summary judgment ruling. <u>See Folsom v. Burger King</u>, 135 Wn.2d 658, 663, 958 P.2d 301 (1998).

835 (2001). The expert admitted there was no physical evidence, "he did not perform a quantitative analysis to support his version of the facts of the accident. . . . [And] he had no way of determining where the point of impact in this accident occurred." Id. This court determined the trial court properly excluded the expert's testimony under ER 702 and ER 703 because it was "speculative and lack[ed] an adequate factual basis." Id. Similarly, in Coogan, the trial court properly excluded expert testimony as overly speculative. 197 Wn.2d 790. The plaintiff was diagnosed with malignant mesothelioma from asbestos exposure, and the expert would have testified that because of plaintiff's history of heavy alcohol use, he may have had advanced cirrhosis that could have reduced his life expectancy. Id. at 798. But the Supreme Court affirmed the exclusion of the evidence as overly speculative, because the expert's opinion was based on death rate statistics for stage 3 cirrhosis patients, and he admitted that "no one, based on those [physical conditions] alone, would stage someone as a stage 3 cirrhosis patient." Id. at 802 (emphasis in original). In both Miller and Coogan, the experts relied on speculation rather than on facts.

Ultimately, Hyland's may dispute the factual basis for Dr. Pietruszka's opinions; however, that differs from establishing that his opinions lack a factual basis. "An objection that an expert employed the methodology in an improper or unscientific manner goes only to the credibility of the expert's opinion, not the admissibility of the expert's testimony." 5B TEGLAND, <u>supra</u>, § 702.19, at 84. At trial, Hyland's is free to challenge the facts on which Dr. Pietruszka relied through

cross-examination or otherwise. But a disagreement as to those facts does not render the expert opinion inadmissible. <u>See</u> ER 705 (the expert "*may* testify in terms of opinion or inference and give reasons therefore . . . [and t]he expert may . . . be required to disclose the underlying facts or data on cross-examination") (emphasis added).<sup>21</sup> Rather, such arguments go to the weight of the evidence, and a jury is perfectly capable of weighing opposing experts' testimony. A "borderline" case "should be decided in favor of admissibility, allowing the jury to decide for itself whether the opinion is reliable." 5B TEGLAND, <u>supra</u>, § 702.27, at 117.

The trial court erred in excluding Dr. Pietruszka's opinion. The opinion on causation should not have been subject to a <u>Frye</u> analysis. Further, it is admissible under ER 702 because it is grounded on facts, not speculation.

#### II. <u>Summary Judgment</u>

Summary judgment is appropriate if no genuine issue exists as to any material fact and the moving party is entitled to a judgment as a matter of law. CR 56(c). In ruling on a summary judgment motion, a trial court must view the evidence and reasonable inferences from it in the light most favorable to the

<sup>&</sup>lt;sup>21</sup> We do not suggest that at summary judgment, an expert may avoid providing the factual basis for their opinions. "ER 705 by its language, is limited to trial testimony, not declaration testimony," and Washington courts have held "an expert's testimony for summary judgment must be supported by the specific facts underlying the opinion." <u>Anderson Hay & Grain Co., Inc. v. United Dominion Indus., Inc.</u>, 119 Wn. App. 249, 259, 76 P.3d 1205 (2003) (citations omitted). Rather, we cite ER 705 to underscore its use of the permissive "may," which suggests a procedural safeguard for the reliability of the expert opinion is cross-examination by the opponent, including regarding the factual underpinnings of the opinion.

nonmoving party. <u>Blue Spirits Distilling, LLC v. Washington State Liquor &</u> <u>Cannabis Bd.</u>, 15 Wn. App. 2d 779, 785, 478 P.3d 153 (2020). "The nonmoving party may not rely on speculation or argumentative assertions that unresolved factual issues remain." <u>Little v. Countrywood Homes, Inc.</u>, 132 Wn. App. 777, 780, 133 P.3d 944 (2006). We review de novo a trial court's decision to grant summary judgment. <u>Lakey</u>, 176 Wn.2d at 922.

In Desranleau's prior appeal, we explained, "To bring a claim under the WPLA, the plaintiff must establish that [their] harm was proximately caused by the condition of the manufacturer's product." Desranleau, 10 Wn. App. 2d at 843 (citing RCW 7.72.030(1)). "A proximate cause of an injury is defined as a cause that, in a direct sequence, unbroken by any new, independent cause, produces the injury complained of and without which the injury would not have occurred." Fabrique v. Choice Hotels Int'l, Inc., 144 Wn. App. 675, 683, 685, 183 P.3d 1118 (2008). Proximate cause consists of two distinct elements—cause in fact and legal causation—both of which the plaintiff must prove. Id. "Cause in fact, or 'but for' causation, refers to the 'physical connection between an act and an injury.' The plaintiff 'must establish that the harm suffered would not have occurred but for an act or omission of the defendant.' " Martini v. Post, 178 Wn. App. 154, 164, 313 P.3d 473 (2013) (citation omitted) (quoting Hartley v. State, 103 Wn.2d 768, 778, 698 P.2d 77 (1985)). Ordinarily, proximate cause is a question for the jury, but it "may be determined on summary judgment where the evidence is

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undisputed and only one reasonable conclusion is possible." <u>Fabrique</u>, 144 Wn. App. at 683 (citing <u>Hartley v. State</u>, 103 Wn.2d 768, 778, 698 P.2d 77 (1985)).

As we held in the prior appeal, the evidence in the summary judgment record includes evidence that Jay'Breon ingested Hyland's cold tablets. <u>Desranleau</u>, 10 Wn. App. 2d at 846. There is evidence that the cold tablets were manufactured using the same process that produced stratification in another Hyland's product, which could have resulted in the concentration of a toxic material in some tablets. There is evidence that GS is a toxic substance and that the Hyland's cold tablets contained GS. Further, there is evidence, through Dr. Pietruszka's testimony,<sup>22</sup> that "to a reasonable degree of medical certainty," the Hyland's cold tablets consumed by Jay'Breon more likely than not caused his death. Viewing the evidence and reasonable inferences from it in the light most favorable to the nonmoving party—here, Desranleau—we determine that there are genuine issues of material fact. We therefore reverse the grant of summary judgment and remand for further proceedings.

#### III. <u>Sanctions</u>

Citing RAP 18.9, Hyland's requests sanctions against Desranleau's counsel for accusing Hyland's counsel of lying to the court. Hyland's contends

<sup>&</sup>lt;sup>22</sup> Desranleau also asserts that, even without Dr. Pietruszka's expert opinion, an inference exists that the stratified tablets "could be lethal at certain quantities" and a "reasonable inference that Jay'Breon ingested a stratified pill that . . . killed him." Given our resolution of the challenge to Dr. Pietruszka's testimony, we need not examine this alternative argument.

that Desranleau's counsel violated court rules, but it does not identify which

rules.

RAP 18.9(a) provides,

The appellate court on its own initiative or on motion of a party may order a party or counsel. . . , who uses these rules for the purpose of delay, files a frivolous appeal, or fails to comply with *these rules* to pay terms or compensatory damages to any other party who has been harmed by the delay or the failure to comply or to pay sanctions to the court. The appellate court may condition a party's right to participate further in the review on compliance with terms of an order or ruling including payment of an award which is ordered paid by the party.

(Emphasis added.) Hyland's does not contend that Desranleau's counsel violated

a RAP to delay or file a frivolous appeal, and Hyland's does not specify any RAP

that Desranleau's counsel violated.<sup>23</sup> We thus deny Hyland's request for

sanctions.

<sup>&</sup>lt;sup>23</sup> Hyland's also requests sanctions against Desranleau's counsel for violating RPC 8.4(d). But RAP 18.9 provides that this court can order sanctions for a party's failure to "comply with *these rules*." (Emphasis added.) Thus, RAP 18.9 does not provide an avenue for this court to impose sanctions for RPC violations.

To support its proposition that we can impose RAP 18.9 sanctions for RPC violations, Hyland's cites In re Welfare of R.H., 176 Wn. App. 419, 430, 309 P.3d 620 (2013), in which Division Two of this court imposed sanctions for an attorney's violation of RPC 3.3(a)(1). There, the attorney violated RPC 3.3(a)(1) by lying to the court. Id. The court did not explain why the RPC violation qualified as a violation of a court rule under RAP 18.9(a). As discussed above, and as Desranleau contends, RAP 18.9 sanctions are applicable only for violating a RAP. And we are not bound by Division Two's decision. See In re Pers. Restraint of Arnold, 190 Wn.2d 136, 138, 410 P.3d 1133 (2018).

Under RPC 8.4(d), a lawyer commits professional misconduct if they "engage in conduct that is prejudicial to the administration of justice." Even if <u>R.H.</u> were binding, Hyland's has not supported its argument—that Desranleau's counsel's accusations were prejudicial to the administration of justice—with citation to the record. RAP 10.3(a)(6); <u>Cowiche Canyon Conservancy v. Bosley</u>, 118 Wn.2d 801, 809, 828 P.2d 549 (1992) (we will not consider arguments unsupported by reference to the record).

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## CONCLUSION

We reverse the trial court's order excluding Dr. Pietruszka's testimony and reverse the grant of summary judgment dismissing Desranleau's claims. We remand for further proceedings consistent with this opinion.

Reversed and remanded.

Chung, J.

WE CONCUR:

Smith.