IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

No. 12-1135

DEBORAH KAY HARRIS

Plaintiff Below, Petitioner,

v.

Appeal from a Final Order of the
Circuit Court of Marshall County
(Civil Action No. 08-C-171M)

CSX TRANSPORTATION, INC.,

Defendant Below, Respondent.

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ASSIGNMENTS OF ERROR

To prevail under the Federal Employers' Liability Act ("FELA"), 45 U.S.C. § 50 et seq., plaintiff-petitioner must show that Ronald Harris's alleged exposures to diesel exhaust caused him to develop multiple myeloma. After the circuit court excluded the testimony of plaintiff's causation experts, the parties jointly moved for entry of summary judgment in favor of defendant-respondent CSX Transportation ("CSXT"). CSXT restates plaintiff's assignments of error as follows:

1. Whether the circuit court correctly concluded that the *Wilt/Gentry/Daubert* standard governs the admissibility of the testimony of plaintiff's causation experts in a FELA case.

2. Whether the circuit court correctly concluded that summary judgment was proper because plaintiff cannot prove causation under the federal FELA causation standard without expert testimony on general causation—*i.e.*, without expert testimony that diesel exhaust is capable of causing multiple myeloma at Harris's alleged exposure levels.

3. Whether the circuit court abused its discretion in concluding that the testimony of plaintiff's causation experts did not satisfy the *Wilt/Gentry/Daubert* reliability standard and therefore was not admissible.

STATEMENT OF THE CASE

A. Plaintiff's FELA Claim

FELA provides a cause of action for injuries sustained by railroad employees in the workplace. *See* 45 U.S.C. § 51. Harris brought suit under that statute alleging that he developed multiple myeloma—a form of cancer in plasma cells, which are found principally in the bone marrow—as a result of occupational exposure to diesel exhaust while employed by CSXT. App. 754. During the pendency of the action, Harris died, and plaintiff was substituted in his place. *Id.*

B. Plaintiff's Causation Theory

In the toxic-exposure setting, causation—an indispensable element of any FELA claim—has

two distinct components that must be proven in sequence: general causation and specific causation. General causation is whether a substance is, at a given level of exposure, *capable* of causing a certain disease in the general population, while specific causation is whether exposure to the substance *in fact* caused the particular plaintiff's disease. *See generally* Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 28 cmt. c (2010); Michael D. Green et al., *Reference Guide on Epidemiology*, in Federal Judicial Center, *Reference Manual on Scientific Evidence* 392 (2d ed. 2000). If the substance does not possess at least the capacity for harm, then it could not logically have been a cause-in-fact of the particular plaintiff's injury. In other words, if there is no general causation, there can be no specific causation. Moreover, causation does not exist in a vacuum; it is specific not only to the *substance* at issue, but also to the *amount* and *method* of exposure as well as the *particular disease* at issue. *See generally Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144-46 (1997); *Tolley v. ACF Indus., Inc.*, 212 W.Va. 548, 559, 575 S.E.2d 158, 169 (2002) (per curiam).

Plaintiff's theory of general causation is that during his employment Harris was exposed to locomotive diesel exhaust—in particular, three of its alleged components, benzene, pristane, and polycyclic aromatic hydrocarbons ("PAHs")—in quantities sufficient to be able to cause multiple myeloma.[1] App. 26, 108 (Infante), 468 (Durie), 754. Plaintiff retained three experts to opine on general causation: Lawrence Goldstein, PhD; Peter Infante, PhD; and Brian Durie, MD. App. 755.

CSXT will describe the opinions of these experts in more detail below. It is, however, undisputed that none of the governmental public health organizations that studies the carcinogenic properties of chemicals—*e.g.*, the International Agency for Research on Cancer ("IARC") or the Environmental Protection Agency ("EPA")—has concluded that diesel exhaust is a cause of

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[1] We say "alleged" components because plaintiff's experts were unable to point to any studies showing that pristane has been found in railroad diesel exhaust. App. 59 (Goldstein), 479 (Durie); *see also* App. 66 (Goldstein), 419. Likewise, diesel contains only "low" levels of benzene, App. 478 (Durie)—less, for example, than is found in gasoline, App. 136 (Infante); *see also* App. 394, 415.

multiple myeloma in humans. As plaintiff's experts conceded, neither "IARC nor EPA has identified the railroad industry as a cancer-causing industry," and neither has produced a "single document ... that says that diesel exhaust causes multiple myeloma." App. 52-53 (Goldstein); *see also* App. 134 (Infante: "I don't think that ... IARC said it was proven to cause it."). Indeed, Goldstein was unaware of "*any organization* ... that practices good science" that has concluded that "multiple myeloma is caused by occupational exposure to diesel exhaust." App. 53 (emphasis added).

1. Goldstein's opinions and methodology

Goldstein's sole source of income is serving as an expert for plaintiffs in litigation. App. 49-50. His area of expertise is animal toxicology, not human epidemiology; in other words, he is *not* an expert on the causes of any human disease. App. 50-51. He was asked to look only at the "biological plausibility" of the assertion that diesel exhaust could cause cancer in any body part with a blood supply (including the bone marrow, where multiple myeloma develops). App. 21, 53-54. Goldstein agreed that, in order to go beyond mere plausibility and evaluate actual causation, "good science" required "more information specifically addressed to [that] issue." App. 55-56.

Although Goldstein opined that it was biologically plausible that exposure to diesel exhaust has the potential to cause cancer generally (App. 54-55), he conceded that he was unaware of even a *single* study that showed an animal developing multiple myeloma in particular after being exposed to diesel exhaust. App. 62-63. He admitted that, "with [respect] to [the] multiple myeloma outcome, [he was] still not aware of an animal system that exists." App. 63; *see also* App. 67 ("Q: You have yet to be able to consider the first ... animal study[] relating to diesel exhaust and multiple myeloma in an animal because it hasn't been done yet, right? A: "That's correct.").[2] Goldstein agreed that he had formed his opinion about biological plausibility "without being able to direct [the Court] to a single

[2] Another of plaintiff's experts confirmed that there have been no reported studies in which an animal has developed multiple myeloma from diesel exhaust exposure. App. 474 (Durie).

animal study or animal that developed multiple myeloma." App. 63-64.

Goldstein further acknowledged that it is "better to evaluate an entire mixture rather than the purported carcinogenicity of individual compounds or constituents." App. 64. Yet, because he knew of no study looking at *whole* diesel exhaust that supported his opinions, Goldstein instead relied on studies in which animals were exposed to purported *constituents* of diesel exhaust, such as pristane and PAHs. But the animal studies Goldstein cited did not involve exposures comparable to those that Harris may have experienced. Rather, they involved different substances, different quantities, and/or different intake routes. Moreover, although they found *other* forms of cancer, none found multiple myeloma—the type of cancer from which Harris suffered.

As for pristane, Goldstein acknowledged that he was unaware of *any study* that had found pristane in diesel exhaust from railroad engines. App. 59.[3] Nevertheless, Goldstein relied upon a study (the "Potter study") in which specially bred mice who were *injected* with pristane directly in the peritoneum (*i.e.*, the membrane that forms the lining of the abdominal cavity) later developed plasmacytomas. App. 39-40, 259 (Goldstein's report), 418 (Durie). A plasmacytoma is a single plasma cell tumor that can *progress to* (but is not itself) multiple myeloma; in fact, the mice injected with pristane never developed multiple myeloma. App. 63 (Goldstein), 474 (Durie). And, of course, if Harris had been exposed to pristane from locomotive diesel exhaust, it would have been through inhalation not injection. But as one of defendant's experts testified without contradiction, there is no literature whatsoever that shows that *inhaled* pristane can cause any kind of cancer, let alone multiple myeloma. App. 487-488 (Green). Goldstein even admitted that the IARC removed pristane from its list of chemicals targeted for further study because "the amount of animal data specifically relating pristane to cancer was considered to be too limited" to warrant additional investigation. App. 61.

[3] The kind of diesel engine producing the exhaust makes a difference. As Goldstein stated, "diesel exhaust is not a single entity even within the idea of diesels," and that means that it is not "proper to talk about diesel exhaust as" a unitary concept. App. 65-66.

As for PAHs—which are a family of chemical byproducts of the "incomplete combustion of carbon-based" matter, and are found in, *inter alia*, engine exhaust, cigarette smoke, and the smoke from a wood fire (App. 12, 15, 57-58 (Goldstein); *see also* App. 171 (Shields))—Goldstein opined that certain PAHs had been found to cause certain forms of cancer in animals. App. 15.[4] He relied principally on studies in which mice *ingested* coal tar, which contains a mixture of PAHs, and then developed various forms of cancer—although notably *not* multiple myeloma. App. 27, 36, 54, 63. Goldstein also relied on a study (the "Van Den Eeden study") in which mice that were fed coal tar exhibited chromosomal damage supposedly "consistent" with chromosomal changes associated with multiple myeloma. App. 68-69. But he conceded that the mice in the Van Den Eeden study never developed multiple myeloma and that mice do not even have the same number of chromosomes as humans. App. 70. Goldstein also acknowledged that a mouse ingesting coal tar was obviously different in many dimensions than a human inhaling diesel exhaust. App. 76-77. In the end, Goldstein agreed that he had never seen a "study, animal or human, that concluded that PAHs in diesel exhaust cause multiple myeloma." App. 67.

2. Infante's opinions and methodology

Infante, the second of plaintiff's experts, is an epidemiologist trained in etiology. App. 78, 81. According to Infante, epidemiology can establish only an *association* between a chemical and a particular disease; a *causation* opinion, Infante testified, requires "interpretation" and "professional judgment." App. 88-89. Infante agreed that, despite this interpretive element, a "professional causation judgment must still be based on good science to be a reliable judgment." App. 128. The

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[4] Goldstein acknowledged that cigarette smoke—which everyone recognizes does not cause multiple myeloma, App. 479 (Durie); *see also* App. 217-218 (Shields)—also contains PAHs and, indeed, Goldstein could not identify a single PAH that was present in diesel exhaust that was not also present in cigarette smoke. App. 57; *see also* App. 170, 219 (Shields) (explaining that cigarette smoke contains all the same identified carcinogens as diesel exhaust), 487 (Green) (explaining that there are higher levels of PAHs in cigarette smoke than in diesel exhaust).

Bradford-Hill framework supplies an appropriate scientific basis for arriving at a causation opinion. App. 467 (Durie); *see also* App. 181-187 (Shields).

a. The Bradford-Hill considerations

To borrow plaintiff's words, the Bradford-Hill considerations can be "summarized as strength, consistency, specificity, temporality, biological gradient (dose-response), plausibility, coherence, experiment and analogy." Plf. Br. 5 & n.7.

The *strength* of an association is measured in terms of "relative risk"; for example, when an epidemiological study reports a relative risk of 2.0, that means that the rate at which the disease develops in a population that had been exposed to the substance (at a given dose) is twice the rate for a normal, unexposed population. App. 90 (Infante). Conversely, when the relative risk is 1.0, that means that the population exposed to the substance developed the disease at the *same rate* as the unexposed population, and there is "no elevated risk." *Id.* Infante acknowledged that the fact that an elevated risk is found in a single epidemiological study does *not* automatically mean there is a causal association. *Id.* For example, that result could have been the result of random chance; thus, by accepted "convention," a result is considered "statistically significant" only if the so-called "P value"—the probability that the observed result would have occurred because of chance—is below 0.05. App. 90-91; *see also* App. 169, 228-230 (Shields) (explaining that the "convention" and "acceptable scientific practice" is to interpret elevated risks that are not statistically significant—*i.e.*, those with P values greater than 0.05—as *not* supporting a causal association). Infante agreed that, standing alone, a study that "wasn't statistically significant ... wouldn't tell you much." App. 92.

The Bradford-Hill criterion of *consistency* compares the results of different epidemiological studies—that is, whether the finding of an elevated risk has been reproduced by different researchers in different contexts. App. 93-94 (Infante). Infante tried to have it both ways. He asserted that "consistency *adds* to ... causality, but inconsistency doesn't necessarily *detract* from it."

App. 94 (emphasis added). But as CSXT's expert explained, consistency "is really critical," because it provides "confidence" that a causal relationship actually exists. App. 182-183 (Shields). In other words, just as a patient would probably not want to take an "antibiotic that's been studied in ten different studies" and has worked in only "two of them, but ... [not] the other eight," a reliable causation opinion cannot ignore inconsistency in the studies. App. 183-184 (Shields).

Another important component of the Bradford-Hill framework is "dose-response." This, in Infante's words, is the "very powerful" notion that *if* a causal association is real—*i.e.*, if exposure to a certain substance actually does increase the risk of a certain disease—then the "more exposure you have, the higher is the risk." App. 95; *see also* App. 184 (Shields). Thus, if a causal relationship exists, one would expect epidemiological studies to find that increased exposure to the substance is correlated with an increased risk of the disease. If a study does not find evidence of a dose-response relationship, then its findings might be the result of chance alone even if it finds a relative risk greater than 1.0 and even if it is otherwise statistically significant. App. 177, 184-185 (Shields). That is because five out of every 100 studies that find a relative risk greater than 1.0 and have a P-value of 0.05 will *still*, as a result of random chance, turn out to be false positives. App. 184 (Shields).

Finally, even when there is a positive dose-response and an elevated relative risk, that does not mean that *any* amount of exposure to the substance will cause the disease; at lower (or background) doses, there might be no adverse health effects. App. 177 (Shields). There is no "information on dose in any of the epidemiological studies related to diesel exhaust," because, as Infante admitted, none of the researchers "ever measured it." App. 150 (Infante).

b. Infante's reliance on inconclusive and selective data.

Although Infante opined that there is a "significant association ... between diesel exhaust exposure and risk of multiple myeloma" (App. 105), even he was unwilling to say that "it's been establish[ed] that there's a ***causal*** connection." App. 153-154 (emphasis added).

As a preliminary matter, Infante agreed that for a study to support a causal interpretation it cannot consider cancers generally but must instead look at the particular "disease of interest"—here, multiple myeloma. App. 110 ("[I]f you're not evaluating for the exposure in the disease of interest, then it doesn't provide any information."). And it also bears reminding that engine exhausts cannot be treated collectively; gasoline exhaust is not the same as diesel exhaust, and diesel exhaust from a tractor is not the same as diesel exhaust from a locomotive. *E.g.*, App. 65-66 (Goldstein) (explaining why it is not "proper to talk about diesel exhaust as" a single concept), 136, 150 (Infante).

The particular sources and studies upon which Infante relied will be addressed in turn:

- The Sonoda article (App. 341): According to Infante, this article found an "elevated risk of multiple myeloma related to exhaust gases." App. 113. But this article considered "both diesel exhaust and gasoline exhaust." *Id.* Indeed, Infante confirmed on cross examination that the word "diesel" was not even *mentioned* in the Sonoda article, which only considered exhaust gasses generally. App. 141-142; *see also* App. 343-345 & fig. 4. Elsewhere, the article found that there is actually a *decreased* risk of multiple myeloma in benzene-exposed workers. App. 145 (Infante), 343 & fig. 1.

- The Schottenfeld treatise (App. 335): In asserting a link between diesel engine exhaust and multiple myeloma, the treatise referenced the Sonoda article, discussed above, and the Boffetta, and Lee articles, discussed below. App. 115 (Infante); *see also* App. 335. Elsewhere, the treatise states that any connection between "occupational exposure to benzene [and] ...myeloma incidents is *contradicted* by largely *negative* results from [other] studies ... arguing *against* a [role] of benzene." App. 139 (Infante) (emphasis added).[5]

- IARC Technical Publication No. 42 (App. 297): According to Infante, this report identified a "link" between diesel exhaust and multiple myeloma. App. 118.[6] But the only reference cited in the report in support of that proposition is the Lee article, discussed below. App. 309; *see also* App. 135 (Infante). And Infante acknowledged that the existence of a possible "link" was *not* the same as having established an association, much less causation. App. 132, 134.

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[5] Infante claimed that Schottenfeld was out of date, but the studies to which he pointed to support that contention involved industrial workers who were exposed to pure benzene for years, which Infante conceded was nothing like Harris's exposure to diesel exhaust in this case. App. 140.

[6] Infante erroneously stated that Publication 42 was drafted by a "technical expert group" at IARC. App. 118. In fact, the publication was drafted by just two reviewers. App. 496 (Green). And far from making a causation judgment, Publication 42 was on its face intended to identify outstanding "research needs." App. 297; *see also* App. 235 (Shields).

- The 1989 Boffetta article: This study found that railroad workers had a *six-fold* increased risk of multiple myeloma, but it was based on only five sample cases. App. 324, 335, 410. CSXT's expert testified—without contradiction—that such a massive increase in risk was could not be scientifically valid because, if it were in fact true, there would be a "huge epidemic of myeloma" and "every study" of railroad workers would detect it. App. 186, 195-197, 410 (Shields). However, these other studies show nothing of the sort. App. 198, 409-410 (Shields).

- The Lee article (App. 336): This article stated that "occupational exposure to diesel exhaust in the Swedish construction industry *may* present a small risk of multiple myeloma." App. 134 (Infante) (emphasis added). Infante admitted that the authors of that paper acknowledged that the "lack of an exposure response [*i.e.*, dose-response] trend tempers our ability to draw clear conclusions." App. 134, 338; *see also* App. 337 ("Relative risks ... did not rise with increasing level of exposure."). He admitted, too, that the article's statement that "further research is needed to substantiate these findings" showed that the authors were *not* making a "declarative statement about causation." App. 149.

- The Sjogren letter: This letter "recommend[ed]" the study of diesel exhaust in connection with multiple myeloma and suggested a "possible link" between diesel exhaust and pristane, but included no basis for these suggestions beyond the Lee article, discussed *supra*. *See* App. 125 (Infante), 419.

- The Semenciw study: This study found that workers on farms that spent more money to purchase diesel fuel had a higher risk of multiple myeloma. App. 151 (Infante). Infante admitted, however, that farms' uses of diesel (for heating and tractors, for example) did not correspond to the locomotive diesel exhaust to which Harris was exposed. App. 150-151. Indeed, the phrase "diesel exhaust" does not appear in the Semenciw study. App. 491-492 (Green). Moreover, the study found that the highest risk for myeloma was associated with the "*lowest* purchase of [diesel] fuel oil" and a high use of fertilizer. App. 492 (Green).

- Infante's meta-analysis (App. 322-327): Infante's meta-analysis included 14 papers, but he conceded that many of the underlying papers either did not mention diesel exhaust, let alone railroad diesel exhaust, or had "limited power" and considered only a small number of cases. App. 147-150 (Hansen and Doll).[7]

No less revealing than the studies that Infante relied upon are those that he ignored. Indeed, although Infante denied having "cherry picked" his sources (App. 108-109), the evidence is to the contrary. Infante's selective consideration of the available data is, for example, evident in his meta-

[7] Infante also mentioned the Potter study (involving pristane-injected mice) discussed above, but had nothing new to say about it. App. 125.

analysis, which *included* many studies that did not even involve diesel exhaust or railroad workers but inexplicably *excluded* the 2001 Boffetta study, which contained information specific to both the particular substance (*i.e.*, diesel exhaust) and the particular population (*i.e.*, railroad workers) at issue here. App. 606-615. That study looked at every adult in Sweden, and based on that large sample, concluded that there was *no increase* in multiple myeloma from exposure to diesel exhaust—the relative risk was 0.98. App. 201-202 (Shields), 412-413 (Shields's report), 490-491 (Green); *see also* App. 609 tbl. 2. That conclusion, moreover, is consistent with a great majority of the epidemiological studies of diesel-exposed workers, which Infante's meta-analysis also failed to include. App. 192, 203 (Shields).[8]

3. Durie's opinions and methodology

Durie, the third of plaintiff's experts, is a board-certified oncologist and hematologist. App. 464. He identified his task as determining whether "these particular chemicals" (*i.e.*, the purported constituents of diesel exhaust: benzene, PAHs, and pristane) "cause this particular cancer" (*i.e.*, multiple myeloma). App. 467.[9] However, he had no idea about the actual *amounts* of these substances contained in diesel exhaust, beyond the fact that diesel exhaust (purportedly) contains "something that," in his view, "can cause multiple myeloma." App. 770.

At any rate, Durie relied on essentially the same sources as Goldstein and Infante. *E.g.*, App. 467 (IARC Technical Publication 42), 468 (Potter study in which mice were injected with pristane),

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[8] Infante also claimed that he was not familiar with the EPA's Health Assessment Document for Diesel Engine Exhaust (App. 138)—which systematically reviewed all of the animal studies involving diesel exhaust and concluded that *none* of them had shown that diesel exhaust can cause multiple myeloma (*id.*)—even though he claimed to have looked at animal studies (App. 121), and even though plaintiff's other experts knew of it. App. 23 (Goldstein), 474 (Durie).

[9] Durie also stated that nickel was present in diesel exhaust and that nickel triggered the production of a "growth factor" for myeloma. App. 468. He recognized, though, that nickel could have this effect only "[o]nce [the patient] ha[s] [a] myeloma cell in the body." App. 466-467. In other words, nickel does not itself *cause* myeloma; at most, it "increases the ability of" already existing "myeloma cells to grow and expand." App. 469 (Durie).

469 (Durie would "rely on what [the Court] heard from Dr. Goldstein" with respect to the animal studies), 471 (Durie "would rely on [Infante's] review" of the epidemiological studies). Durie admitted that "animal studies are limited by differences between animal and human physiology." App. 473. Like Goldstein, Durie was unable to identify *any* study in which animals exposed to diesel exhaust developed multiple myeloma. App. 474. Durie admitted, moreover, that science had yet to establish a link between pristane exposure and multiple myeloma in human beings and that any link between benzene and multiple myeloma remained controversial. App. 481 ("Q: Is that [study in which mice were injected with pristane] enough for you to say it causes myeloma in people? A: Not at all."). Durie also acknowledged that there is no evidence of a "cancer cluster" of multiple myeloma patients "on the railroad." App. 480.

Beside the epidemiological studies reviewed by Infante and the animal studies reviewed by Goldstein, Durie purported to rely on his personal experience treating patients and a study (the "Smith study") analyzing chromosomal changes from benzene exposure. According to Durie, many of the multiple myeloma patients (*e.g.*, a dolphin photographer) in his "clinical practice" anecdotally reported exposures to a diverse array of chemicals. App. 470-471. But on cross-examination, Durie admitted that he did not take detailed occupational histories of his patients and that these anecdotes were just "piece[s] of information" for forming a hypothesis, *not* anything on which to premise a causation opinion. App. 476-477. As for the Smith study, Durie tried to draw a connection between Harris's case of multiple myeloma—which was characterized by changes on chromosomes 6, 13, 17, and 20 of his plasma cells—and supposedly similar chromosomal changes (to chromosomes 3, 6, 10, 13) seen in the Smith study among individuals in the chemical industry. App. 470, 578. But on cross-examination, Durie conceded that these changes were not "unique or specific" to benzene exposure and that Harris's own exposure to diesel exhaust was not comparable to exposure to "pure benzene in the range of about 30 parts per million," which was the exposure level examined by the Smith

study. App. 481; *see also* App. 220-221 (Shields) (discussing Smith study; explaining that there is no pattern of chromosomal damage specific to benzene exposure).

Durie purported to employ the Bradford-Hill framework to arrive at his causation opinion. App. 467. But, as explained above (*see supra* at 7), an important component of the Bradford-Hill framework is examining whether there is a "dose-response"—because an observed association more reliably reflects a causal association when the risk increases with the "more exposure you have." App. 95 (Goldstein). Durie, however, acknowledged that diesel exhaust contains only low levels of benzene, and he did not know how much PAHs or pristane was in diesel exhaust. App. 478-479. Moreover, he had no explanation for how diesel exhaust could possibly cause multiple myeloma if cigarette smoke—which contains more benzene, PAHs, and pristane than diesel exhaust—did *not* cause multiple myeloma beyond asserting that there were unspecified "special situations and special additional factors" in play. App. 479; *see also* App. 219 (Shields), 493 (Green).

Finally, Durie was forced to concede that in his prior professional work (*i.e.*, when he was *not* testifying as a paid expert), he had not identified diesel exhaust, benzene, PAHs, or pristane as potential causes of multiple myeloma. He has authored a single publication about the causes of multiple myeloma, entitled *The Epidemiology of Multiple Myeloma.* App. 474; *see also* App. 583 (article). That paper lists "radiation," "various chemicals," "environmental chemicals," "breast implants, pacemakers, intro-uterine devices, electrical burns, and dental adhesives" as causes of multiple myeloma. App. 475-476 (Durie). It does not mention diesel exhaust, benzene, PAHs, or pristane. *Id.* Durie also chairs an organization called the International Myeloma Foundation ("IMF"). The IMF does not mention diesel exhaust, benzene, PAHs, or pristane as a possible cause of multiple myeloma on its webpage "What Causes Myeloma," even though that same page lists a number of *other* chemicals (*e.g.*, Agent Orange and petrochemical cleaning solvents). App. 477 (Durie), 588.

C. Proceedings Below

In January 2011, at the conclusion of expert discovery, CSXT filed a motion to exclude the testimony of Durie, Infante, and Goldstein. App. 755. The circuit court held a two-day evidentiary hearing. *Id.* The circuit court began the first day of the hearing by obtaining the on-the-record agreement of *both* parties that a "*Gentry/Daubert*" analysis was proper because the "testimony proffered by the Plaintiff is scientific," and that the "burden [was] on the Plaintiff[] to prove ... by a preponderance of the evidence" that the expert testimony was admissible under the *Gentry/Daubert* standards, App. 4-5. During the hearing, plaintiff presented the testimony of his proposed experts and CSXT presented the testimony of its experts, Laura Green, PhD, and Peter Shields, MD. App. 7-77 (Goldstein), 78-155 (Infante), 157-236 (Shields), 464-482 (Durie), 482-499 (Green).

On August 15, 2012, the circuit court entered three orders excluding the testimony of plaintiff's general-causation experts and precluding them from testifying. App. 759-774 (Durie Order), 776-793 (Infante Order), 795-804 (Goldstein Order).

Durie, the circuit court found, had failed to employ "good science" in reaching the opinion that diesel exhaust can cause multiple myeloma. App. 773. Despite his testimony as a retained expert in this case that diesel exhaust can cause multiple myeloma, Durie had not previously expressed that opinion in his prolific academic writing on the causes of multiple myeloma. App. 773-774. His litigation opinion, the court found, was "unsupported" by the relevant literature, and depended on Infante's opinions, which failed to "employ a methodology grounded in good science." *Id.*

Infante, the circuit court observed, asserted the existence of an association between diesel exhaust and multiple myeloma, but never expressed the opinion that diesel exhaust *causes* multiple myeloma. App. 789. Moreover, methodological weaknesses rendered Infante's assertion of even an association suspect, the circuit court found, because Infante's assertion rested on "studies that lack statistical significance." App. 784. Pointedly, the circuit court suggested that Infante had engaged in

impermissible cherry-picking when he ignored a large study specific to the railroad industry that found no difference in the risk for developing multiple myeloma between railroad workers who had been exposed to diesel exhaust and those who had not. App. 784, 789, 792. And the court noted that Infante claimed to be "wholly unfamiliar" with the EPA's diesel-exhaust Health Assessment (which concluded that none of the animal studies surveyed had found that diesel exhaust can cause multiple myeloma), notwithstanding its central relevance to the issue here. App. 787, 792. "It is not appropriate in a good scientific causation methodology," the circuit court explained, "to ignore or be willfully unaware of contrary evidence." App. 793.

Finally, as for Goldstein, the circuit court noted that he had restricted his opinion to only the "biologic plausibility" of diesel exhaust's potential health effects based on animal studies and did not purport to offer an opinion as to general causation in humans. App. 803. The circuit court found that Goldstein was unable to "cite *any* scientific studies supporting his ... opinions regarding diesel exhaust, its constituents[,] and their purported ability to cause multiple myeloma in humans." App. 803-804 (emphasis added). For these and other reasons, the circuit court concluded that Goldstein's opinions were "not grounded on a scientifically valid and properly applied methodology." App. 804.

Without any expert witnesses to support her claim, plaintiff agreed with CSXT to "jointly move[] the Court for entry of summary judgment" in favor of CSXT. App. 754. In plaintiff's words, she "desire[d] the entry of a final order from which" she could appeal the circuit court's *Wilt/Gentry/Daubert* rulings. App. 754 n.1; *see also* Plf. Br. 7 (stating that plaintiff "agreed" to seek entry of judgment so "that the trial court's rulings on [her] experts could be appealed").

On August 21, 2012, the circuit court granted summary judgment in favor of CSXT. The court concluded that, in light of its *Wilt/Gentry/Daubert* rulings, there was "no genuine issue of material fact regarding general causation." App. 756. The court stated that "CSXT argues, and the Plaintiff concedes, that there exists no trial worthy issue to pursue in this regard," which meant that

CSXT was "entitled to summary judgment." *Id.* This appeal followed.

SUMMARY OF ARGUMENT

Plaintiff's first assignment of error is that the circuit court "failed to consider" that this is a FELA case in which, according to plaintiff, a different and lesser standard for the admission of expert testimony purportedly applies. Plf. Br. 1, 7. This assignment of error is waived. Below, plaintiff agreed with the circuit court that the *Wilt/Gentry/Daubert* standard governed the admission of her proposed experts' testimony. *See* Point I.A, *infra.* In any event, the assignment of error is without merit. As this Court has expressly recognized, the causation standard in FELA cases does *not* "mean that in FELA cases courts must allow expert testimony that in other contexts would be inadmissible." *Jenkins v. CSX Transp., Inc.*, 220 W.Va. 721, 731, 649 S.E.2d 294, 304 (2007) (per curiam) (internal quotation marks omitted). Expert testimony that is unreliable under the *Wilt/Gentry/Daubert* standard is inadmissible in a FELA case just as it would be in any other case. In short, although a FELA plaintiff need only prove that the railroad's negligence played a role, however slight, in the plaintiff's injury, a FELA plaintiff still must do so based on reliable, admissible evidence, not junk science. *See* Point I.B, *infra.*

Plaintiff's second assignment of error is that West Virginia law does not require plaintiffs to prove general causation. Plf. Br. 16, 18. This assignment of error fails for a number of independent reasons. To begin with, it too is waived. After the circuit court excluded her general-causation experts, *plaintiff herself* joined in CSXT's motion for summary judgment in order to appeal the court's evidentiary rulings. Having done so, she cannot now complain that summary judgment was not properly entered or that general causation is not a required element of her FELA claim. *See* Point II.A, *infra.* Further, plaintiff is wrong on the merits. Because the *federal* causation standard applies to FELA actions brought in state court—and because that federal standard *does* require both general and specific causation to be established—it is irrelevant that West Virginia cases may not have

defined causation in terms of general and specific causation. *See* Point II.B, *infra.*

Plaintiff's third assignment of error is that the circuit court should not have excluded her proposed experts under the *Wilt/Gentry/Daubert* standard. Although plaintiff casts this argument in terms of whether the circuit court applied the wrong legal standard to its determination (and thereby attempts to secure the benefit of a *de novo* review), the argument is in substance nothing more than an ordinary challenge to the circuit court's factual findings and discretionary judgment. Clearing away the underbrush, the relevant question—as acknowledged by both Infante and Durie—is *not* whether some kinds of engine exhaust can cause some forms of cancer, but rather whether exposure to *railroad diesel exhaust* specifically can cause *multiple myeloma* in particular. *See* Point III.A, *infra.*

As to that question, the circuit court correctly found, plaintiff's experts relied on little more than (1) a handful of cherry-picked epidemiological studies whose findings were equivocal, devoid of dose information, and/or statistically insignificant, and (2) animal studies that did not even involve comparable exposure scenarios. These purported experts, moreover, were unable to explain how the opinion that diesel exhaust can cause multiple myeloma could be reconciled with the undisputed fact that cigarette smoke—which contains, in even *higher* quantities, all of the constituents of diesel exhaust alleged to contribute to multiple myeloma—does *not* cause multiple myeloma. It is clear that plaintiff's experts did not bring to the courtroom remotely the same level of intellectual rigor that they (at least should) apply in their academic or research capacities. In response, plaintiff's brief does little but attack a strawman of its own creation. Plaintiff asserts that the circuit court imposed categorical evidentiary requirements as a condition of admitting expert testimony, and portrays the issue as whether concededly marginal epidemiological or animal studies can *ever* be a proper foundation for a reliable causation opinion. Of course, that is not the issue here—and tellingly, plaintiff never explains how *her experts* reliably could have based *their opinions* on *these inconclusive sources.* Based on a fully developed evidentiary record, the circuit courted acted well within its

discretion in excluding the testimony of plaintiff's experts as unreliable. *See* Point III.B, *infra.*

Further, the circuit court's decision is consistent with the weight of authority, which recognizes the unreliability—and consequent inadmissibility—of the opinion that railroad diesel exhaust exposure causes multiple myeloma. *See, e.g., Richardson v. Union Pacific R.R.*, ___ S.W.3d ___, 2011 WL 4477791 (Ark. Ct. App. 2011); *Mo. Pac. R.R. v. Navarro*, 90 S.W.3d 747 (Tex. Ct. App. 2002). Plaintiff's contrary reliance on *King v. Burlington Northern Santa Fe Ry.*, 762 N.W.2d 24 (Neb. 2009), is misplaced. This Court should "decline to adopt" *King*, which is "not in accord with federal precedent" on the *Daubert* reliability standard, *Richardson*, 2011 WL 4477791, at *13, *19, which this Court has endorsed in other cases. *See* Point III.C, *infra.*

STATEMENT REGARDING ORAL ARGUMENT AND DECISION

Because the circuit court's decision faithfully applied to the specific facts of this case the legal standards that have been authoritatively articulated by this Court in other cases, and because the facts and legal arguments are adequately presented by the briefs and record on appeal, CSXT respectfully submits that the Court's decisional process would not be significantly aided by oral argument. *See* W. Va. R. App. P. 18(a). Oral argument therefore is unnecessary.

STANDARD OF REVIEW

The Court reviews *de novo* the circuit court's decision to grant summary judgment to a party. Syl. pt. 1, *Painter v. Peavy*, 192 W.Va. 189, 451 S.E.2d 755 (1994).

The Court "review[s] evidentiary and procedural rulings of the circuit court under an abuse of discretion standard." *Jenkins*, 220 W.Va. at 726, 649 S.E.2d at 299 (internal quotation marks omitted). In particular, "[w]hether a witness is qualified to state an opinion is a matter which rests within the discretion of the trial court and its ruling on that point will not ordinarily be disturbed unless it clearly appears that its discretion has been abused." *Id.* (internal quotation marks omitted). Only a question of law, such as the "circuit court's *method* of conducting" the "*Daubert/Wilt*

gatekeeper analysis" or whether the circuit court "applied the *proper standard* in determining whether to admit or exclude expert testimony," is subject to *de novo* review. *San Francisco v. Wendy's Int'l, Inc.*, 221 W.Va. 734, 740, 656 S.E.2d 485, 491 (2007) (emphasis added). When the circuit court applies the correct legal standard, however, its ultimate "ruling with respect to the admissibility of expert testimony" is "'a matter within the sound discretion of the trial court, and the trial court's decision will not be reversed unless it is clearly wrong.'" *State v. Ferguson*, 222 W.Va. 73, 77, 662 S.E.2d 515, 519 (2008) (per curiam) (quoting Syl. pt. 1, *Watson v. Inco Alloys Int'l, Inc.*, 209 W.Va. 234, 545 S.E.2d 294 (2001)); *accord State ex rel. Thompson v. Ballard*, 229 W.Va. 263, 728 S.E.2d 147, 153 n.7 (2012) (per curiam) (citing Syl. pt. 6, *Helmick v. Potomac Edison Co.*, 185 W.Va. 269, 406 S.E.2d 700 (1991)).

The abuse of discretion standard is highly deferential. Under it, this Court "will not disturb a circuit court's decision unless the circuit court makes a clear error of judgment or exceeds the bounds of permissible choices in the circumstances." *Gribben v. Kirk*, 195 W.Va. 488, 500, 466 S.E.2d 147, 159 (1995); *see also Jenkins*, 220 W.Va. at 728, 649 S.E.2d at 301. "Only where [the Court is] left with a firm conviction that an error has been committed may [it] legitimately overturn a lower court's discretionary ruling." *Covington v. Smith*, 213 W.Va. 309, 322, 582 S.E.2d 756, 769 (2003).

ARGUMENT

I. THE CIRCUIT COURT APPLIED THE CORRECT STANDARD FOR ASSESSING THE RELIABILITY OF SCIENTIFIC EXPERT TESTIMONY.

Plaintiff asserts that the circuit court should have "been more lenient in permitting expert testimony" given the "lower causation standard" applicable to FELA claims such as hers. Plf. Br. 1, 7, 12. This argument is both waived and without merit.

A. Plaintiff's Assignment of Error Is Not Properly Before This Court.

Plaintiff argues that there is tension "between the ... liberal causation standard applicable under the FELA" and the admissibility and reliability "analysis required by the *Daubert/Wilt* holdings." Plf. Br. 10. Below, however, plaintiff did not argue that anything other than the usual

standard governing the admissibility of expert testimony should be applied by the circuit court. To the contrary, she expressly took the position that a *Wilt/Gentry/Daubert* analysis was proper and that, under that standard, plaintiff bore the burden of showing that the proposed expert testimony was reliable and admissible. The record speaks for itself:

> THE COURT: ... [I]t is proper for a *Gentry/Daubert* analysis insofar as the testimony proffered by the Plaintiff is ... scientific in nature. Is that correct, Mr. Hartley?
>
> MR. HARTLEY (Counsel for Plaintiff): *It is, Your Honor.*
>
> ...
>
> THE COURT: ... The burden is on the Plaintiff[] to prove to the Court by a preponderance of the evidence. Everyone agrees that that's the standard to be applied?
>
> MR. HARTLEY: *Yes, sir.*

App. 4-5 (emphasis added). Having expressly agreed that the circuit court should apply the *Wilt/Gentry/Daubert* analysis, plaintiff never argued that a lesser standard should apply because this is a FELA case. It is too late for her to raise that claim now—she has not merely *forfeited* the point, but affirmatively *waived* it.

Even assuming *arguendo* that there was any error—and, to be clear, there was not (*see infra* pp. 20-24)—*plaintiff* induced any such error by expressly agreeing to application of the *Wilt/Gentry/Daubert* standard. This, therefore, is a picture-perfect example of invited error. The invited error doctrine—a "cardinal rule of appellate review"—"prevents a party from inducing an inappropriate or erroneous response and then later seeking to profit from that error." *State v. Griffy*, 229 W.Va. 171, 727 S.E.2d 847, 855 n.7 (2012) (per curiam) (internal quotation marks omitted). As this Court has repeatedly held, "[a] party simply cannot acquiesce to, or be the source of, an error during proceedings before a tribunal and then complain of that error at a later date." *Hanlon v. Logan Cnty. Bd. of Educ.*, 201 W. Va. 305, 316, 496 S.E.2d 447, 458 (1997) (collecting cases). This Court rigorously and consistently applies the waiver doctrine. One recent decision catalogued no fewer

than ***15*** cases setting forth the "well-established law in this state that '[a] party cannot invite the court to commit an error, and then complain of it.'" *Hopkins v. DC Chapman Ventures, Inc.*, 228 W.Va. 213, 719 S.E.2d 381, 387 (2011) (per curiam) (quoting *Lambert v. Goodman*, 147 W.Va. 513, 519, 129 S.E.2d 138, 142 (1963); collecting cases).

"If any principle is settled in this jurisdiction, it is that, *absent the most extraordinary circumstances*, legal theories not raised properly in the lower court cannot be broached for the first time on appeal." *State v. Miller*, 197 W.Va. 588, 597, 476 S.E.2d 535, 544 (1996). Indeed, even when review is *de novo*, this Court, "for obvious reasons, will not consider ... arguments that were not presented to the circuit court for its consideration." *Powderidge Unit Owners Ass'n v. Highland Props., Ltd.*, 196 W.Va. 692, 700, 474 S.E.2d 872, 880 (1996). "To preserve an issue for appellate review, a party must articulate it with such sufficient distinctiveness to alert a circuit court to the nature of the claimed defect." *State ex rel. Cooper v. Caperton*, 196 W.Va. 208, 216, 470 S.E.2d 162, 170 (1996). Parties "must speak clearly in the circuit court, on pain that, if they forget their lines, they will likely be bound forever to hold their peace." *Id.* This Court has "invoked this principle with a near religious fervor." *Miller*, 197 W.Va. at 597, 476 S.E.2d at 544.

Plaintiff has not even *tried* to show that this claim was preserved below. And, by not alerting this Court to the fact that "the issue was not presented to the lower tribunal," she violated W. Va. R. App. P. 10(c)(3). This Court should hold plaintiff to her waiver and decline to consider the claim.

B. The *Wilt/Gentry/Daubert* Standard Applies In FELA Cases.

If the Court nonetheless elects to reach this claim, it should be rejected on the merits. In a FELA decision—quoted and relied upon by plaintiffs (*see* Plf. Br. 15)—this Court took note of FELA's liberal causation standards and the U.S. Supreme Court's admonition that, under FELA, "'the test of a jury case is simply whether the proofs justify with reason the conclusion that employer negligence played any part, even the slightest, in producing the injury or death for which damages

are sought.'" *Jenkins*, 220 W.Va. at 731, 649 S.E.2d at 304 (quoting *Rogers v. Mo. Pac. R.R.*, 352 U.S. 500, 506 (1957)). But "[t]his does not mean," the Court recognized,

> that FELA plaintiffs need make no showing of causation. ***Nor does it mean that in FELA cases courts must allow expert testimony that in other contexts would be inadmissible.*** It means only that in FELA cases the negligence of the defendant "need not be the sole cause or whole cause" of the plaintiff's injuries.

Id. (emphasis added). In *Jenkins* itself, the Court agreed with the railroad that the circuit court had not abused its discretion when it prohibited the employee's expert from testifying under *Gentry v. Mangum*, 195 W.Va. 512, 466 S.E.2d 171 (1995), on the ground that the expert was not qualified "to give an opinion as to the cause of [the employee's] injury." 220 W.Va. at 731, 649 S.E.2d at 304. And in upholding the exclusion of the plaintiff's expert witness, the Court did not even remotely suggest that a more "lenient" (*cf.* Plf. Br. 12) admissibility standard should apply because *Jenkins* was a FELA case. Accordingly, *Jenkins* requires rejection of plaintiff's first assignment of error.

Starting from first principles, *Jenkins* was plainly correct on this score. Plaintiff's argument to the contrary conflates the question of evidentiary *sufficiency* under FELA with the threshold question under *Wilt/Gentry/Daubert* of whether the expert's opinions are *reliable* enough to be admissible in the first instance. Plaintiff cites a plethora of cases standing for the unremarkable propositions that FELA claims are subject to a liberal standard of causation and should go to the jury if the "'proofs justify with reason the conclusion that employer negligence played any part, even the slightest, in producing the injury or death for which damages are sought.'" Plf. Br. 9 (quoting *Rogers*, 352 U.S. at 506); *see generally id.* at 8-10, 15-16.[10] All this is true enough, but also quite beside the point.

Unless a plaintiff has at least *some* admissible evidence on a requisite element of his or her claim—and there is no dispute that causation is an element of a FELA claim (*see infra* pp. 26-29)—

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[10] FELA's "relaxed standard of causation" (*Consol. Rail Corp. v. Gottshall*, 512 U.S. 532, 543 (1994)), requires more than "mere 'but for' causation," yet something less than traditional proximate causation (*CSX Transp., Inc. v. McBride*, 131 S. Ct. 2630, 2641 & n.9 (2011)).

no jury case has been made, regardless of how "relaxed" (or not) that element may be. And evidence that is inadmissible is simply not evidence that the jury (or other factfinder) can even consider, and thus cannot aid a plaintiff in satisfying even the FELA standard for sufficiency of the evidence. *See, e.g.*, *Reed v. Wimmer*, 195 W.Va. 199, 204 n.4, 465 S.E.2d 199, 204 n.4 (1995) (jury must be instructed to "disregard the inadmissible evidence"); *State v. Davis*, 176 W.Va. 454, 465-65, 345 S.E.2d 549, 560 (1986) (explaining that sufficiency-of-the-evidence determination is conducted by looking at the record after the "inadmissible evidence [is] removed") (internal quotation marks omitted). As the U.S. Supreme Court has made clear in the *Daubert* context, "[i]nadmissible evidence contributes *nothing* to a 'legally sufficient evidentiary basis'" for a jury verdict and judgment. *Weisgram v. Marley Co.*, 528 U.S. 440, 454 (2000) (emphasis added). Thus, when the "expert testimony plaintiff introduced was unreliable, and therefore inadmissible, under the analysis required by *Daubert*," and that results in an absence of proof on a required element of the plaintiff's case, the defendant is entitled to judgment as a matter of law. *Id.* at 443. This is true in a FELA case as in any other.

Under West Virginia law, the well-established standards for determining the relevance and reliability—and thus admissibility—of scientific expert testimony are set forth in *Wilt v. Buracker*, 191 W.Va. 39, 443 S.E.2d 196 (1993), and *Gentry v. Mangum*, 195 W.Va. 512, 466 S.E.2d 171 (1995).[11] These cases "impose a 'gatekeeper' duty upon trial courts to screen scientific expert opinions to ensure they are both relevant to the case *and* based upon reliable methodologies." *San Francisco*, 221 W.Va. at 741, 656 S.E.2d at 492 (emphasis added). Neither *Wilt* nor *Gentry* nor *San Francisco* provides any support for the view that what counts as "reliable" varies based on the underlying type of legal claim. That view, moreover, makes no sense: Either the expert has applied a "scientifically valid methodology or mode of reasoning" or he has not. *San Francisco*, 221 W.Va. at 742, 656 S.E.2d at

[11] Because in "*Wilt*, this Court adopted a standard similar to that established by the United States Supreme Court in *Daubert*," both West Virginia and federal cases are often cited with respect to expert admissibility issues. *San Francisco*, 221 W.Va. at 741, 656 S.E.2d at 492.

493. Junk science is junk science, regardless of whether it is offered in a FELA case or any other.

Indeed, the very cases plaintiff relies on confirm that "*Daubert* is properly applied in a FELA case." *Savage v. Union Pacific* R.R., 67 F. Supp. 2d 1021, 1028 (E.D. Ark. 1999) (*cf.* Plf. Br. 10, 14); *see also, e.g., Wills v. Amerada Hess Corp.*, 379 F.3d 32, 47 (2d Cir. 2004) ("[T]he standards for determining the reliability ... of expert testimony are *not* altered merely because the burden of proof is relaxed.... [E]ven where, as here, plaintiff faces a relaxed burden of proof with regard to causation, the ... admission of expert testimony is nonetheless governed by the strictures of Rule 702 and *Daubert*.") (emphasis added; *cf.* Plf. Br. 10-11); *Claar v. Burlington N. R.R.*, 29 F.3d 499, 503 (9th Cir. 1994) ("The standard of causation under FELA and the standards for admission of expert testimony ... are distinct issues and do *not* affect one another.") (emphasis added; *cf.* Plf. Br. 15).[12] It is, moreover, the view held by the overwhelming majority of courts to have considered the issue. *See Taylor v. Consol. Rail Corp.*, 114 F.3d 1189 (table), 1997 WL 321142, at *6-*7 (6th Cir. 1997) (per curiam) ("[i]t is well established that the [admissibility of expert testimony] is controlled—even in cases arising under FELA—by" the *Daubert* reliability standard); *Bowers v. Norfolk S. Corp.*, 537 F. Supp. 2d 1343, 1352 (M.D. Ga. 2007) ("[T]he admission of expert testimony is controlled—even in FELA cases—by the

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[12] *In re Conrail Toxic Tort FELA Litigation*, 1998 WL 465897 (W.D. Pa. 1998), addressed the Third Circuit's decisions in *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994) (cited in Plf. Br. 12), and *Hines v. Consolidated Rail Corp.*, 926 F.2d 262 (3d Cir. 1991) (cited in Plf. Br. 11). The *Conrail* court ultimately concluded that

> *Daubert's* standard of admissibility "extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case." Thus, if the expert's conclusion—or any inferential link that undergirds it—fails under *Daubert* to provide *any* evidence of causation, it must be excluded, even under *Hines'* liberal approach to admissibility.

1998 WL 465897, at *6 (quoting *In re Paoli*, 35 F.3d at 743). Subsequent cases from district courts in the Third Circuit have cast doubt on whether the *Hines/Paoli* approach survives *Daubert*. *See, e.g., Wicker v. Consol. Rail Corp.*, 371 F. Supp. 2d 702, 713-15 (W.D. Pa. 2005) (analyzing *Daubert* motion "without any question of admissibility being affected by the standards of causation set forth under the FELA"); *In re Paoli R.R. Yard PCB Litig.*, 2000 WL 274262, at *2 (E.D. Pa. 2000) ("[T]he FELA causation standard does not lower the burden of admissibility here.").

Federal Rules of Evidence and *Daubert*."), *aff'd per curiam*, 300 F. App'x 700 (11th Cir. 2008); *Johnson v. Union Pac. R.R.*, 2007 WL 2790699, at *1 (D. Neb. 2007) ("The *Daubert* standard ... is equally applicable to FELA and non-FELA actions."); *Marsch v. Exxon Mobil Corp.*, 2005 WL 2246006, at *2 (E.D. Mo. 2005) ("standard for admission of expert testimony in FELA cases is controlled by ... *Daubert* and is not affected by the relaxed standard of proof in FELA cases").

In this case, the circuit court concluded that the testimony of plaintiff's causation experts was unreliable under the *Wilt/Gentry/Daubert* standard and excluded their opinions on that basis. App. 774 (Durie), 793 (Infante), 804 (Goldstein). Because the circuit court applied the correct legal standard, plaintiff's first assignment of error is without merit.

II. BECAUSE FELA PLAINTIFFS MUST PROVE GENERAL CAUSATION, THE CIRCUIT COURT PROPERLY GRANTED SUMMARY JUDGMENT TO CSXT.

In her second assignment of error, plaintiff asserts that she need not present any evidence of general causation—*i.e.*, evidence that exposure to the substance in question is *capable* in principle of causing the alleged injury—in order to prevail on her FELA claim.[13] Plf. Br. 16. This argument is waived and meritless under the governing federal standards.

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[13] Plaintiff also seemingly asserts in passing that expert evidence on causation is *never* required in a FELA case because the "jury" can by itself make a "legal determination regarding causation." Plf. Br. 11 (quotation marks omitted). This argument is waived for the reasons explained in the text (*infra* at pp. 25-26). It also is plainly incorrect. This Court's decision in *Jenkins* is directly to the contrary. After affirming the exclusion of the employee's experts, the Court went on to affirm the dismissal of his FELA claim on the ground that he "was unable to provide sufficient evidence" that he developed encephalopathy "as a result of excessive exposure to occupational solvents." 220 W.Va. at 724, 732, 649 S.E.2d at 297, 305. That result is in accord with cases from this and other courts. *See, e.g., Banfi v. Am. Hosp. for Rehab.*, 207 W.Va. 135, 141, 529 S.E.2d 600, 606 (2000) (per curiam) (holding that "it is generally acknowledged that such [expert] testimony is necessary" when the plaintiff's claims involve "technical medical" issues); *Wills*, 379 F.3d at 50 ("Absent admissible expert testimony on the issue of causation, [the FELA plaintiff] was unable to sustain her burden to prove causation."); *Claar*, 29 F.3d at 504 (because "drawing a particular conclusion [in a toxic-exposure case] requires specialized knowledge," "expert testimony is necessary to establish even that small quantum of causation required by FELA"). When, as here, "there is no obvious origin to an injury and it has 'multiple potential etiologies, expert testimony is necessary to establish causation'" in a FELA case. *Myers v. Ill. Cent. R.R.*, 629 F.3d 639, 643 (7th Cir. 2010) (quoting *Wills*, 379 F.3d at 46).

A. Plaintiff's Assignment Of Error Is Not Properly Before This Court.

Plaintiff admits that she "*agreed* with [CSXT] to *jointly* move the trial court for entry of summary judgment in favor of [CSXT] so that the trial court's rulings on [her] experts could be appealed." Plf. Br. 7 (emphasis added); *see also* App. 754 ("the parties ... jointly move[] for entry of summary judgment"). In other words, rather than *oppose* CSXT's motion for summary judgment, plaintiff affirmatively acquiesced in it, so as to tee up her "appeal [of] the [circuit] Court's preclusion of her expert witnesses." App. 754 n.1. The summary judgment order—which was explicitly "Approved By" plaintiff (App. 757)—concluded that, with the exclusion of plaintiff's expert witnesses, there was no "evidence supporting the Plaintiff's general causation burden" and hence "no genuine issue of material fact regarding general causation." App. 755-756. Thus, CSXT was "entitled to summary judgment" given the absence, which "Plaintiff concede[d]," of any "trial worthy issue to pursue in [that] regard." App. 756.

Having affirmatively acquiesced to entry of summary judgment based on the absence of admissible general causation evidence, Plaintiff cannot now argue that general causation is not "a separate element of a plaintiff's required proof of causation" (Plf. Br. 19-20) and that the circuit court should therefore have allowed her case to proceed notwithstanding the lack of admissible general causation evidence. That argument is waived for essentially the same reasons as set forth *supra* at pp. 18-20. "'A party simply cannot acquiesce to ... an error during proceedings before a tribunal and then complain of that error'" on appeal. *Hanlon*, 201 W.Va. at 316, 496 S.E.2d at 458 (citing *Crabtree*, 198 W.Va. at 627, 482 S.E.2d at 612). The appropriate way for plaintiff to have advanced the argument she now raises was by opposing summary judgment on the ground that general causation need not be proven, and by setting forth the authority upon which she now

relies.[14] She failed to do this below, and "legal theories not raised properly in the lower court cannot be broached for the first time" before this court. *Miller*, 197 W.Va. at 597, 476 S.E.2d at 544.

B. FELA Plaintiffs Must Prove General Causation Under Federal Law.

Plaintiff's second assignment of error is also without merit. She assumes that "West Virginia law" governs the causation standard for her FELA claim. Plf. Br. 18-19. But that is not so. *Federal* law governs, and requires evidence of general causation.

Although "FELA provides for concurrent jurisdiction of the state and federal courts, ... substantively FELA actions are governed by *federal* law." *Norfolk S. Ry. v. Sorrell*, 549 U.S. 158, 165 (2007) (emphasis added); *see also Jenkins*, 220 W.Va. at 298 n.5, 649 S.E.2d at 725 n.5 ("[S]ubstantive issues under the Federal Employers' Liability Act are determined by the provisions of the statute and interpretative decisions of the Federal Employers' Liability Act given by the *federal* courts.") (emphasis added; internal quotation marks omitted); *McGraw v. Norfolk & W. Ry.*, 201 W.Va. 675, 679, 500 S.E.2d 300, 304 (1997) ("[W]e are constrained to follow federal case law interpreting FELA."). "[O]nly if federal law controls can the federal Act be given that uniform application throughout the country essential to effectuate its purposes." *Dice v. Akron, Canton & Young R.R.*, 342 U.S. 359, 361 (1952). Moreover, there can be no question that the causation standard in a FELA

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[14] Plaintiff may note that her Response to Defendant's Motion to Exclude Evidence, Or, In The Alternative, For A *Daubert/Gentry* Hearing asserted that a plaintiff is not required to establish general causation. This assertion did not preserve the issue for review for two independent reasons. *First*, it was unsupported by argument or citation to authority. *See State Dep't of Health v. Robert Morris N.*, 195 W.Va. 759, 765, 466 S.E.2d 827, 833 (1995) ("A skeletal 'argument,' really nothing more than an assertion, does not preserve a claim .... Judges are not like pigs, hunting for truffles buried in briefs.'") (internal citations and quotation omitted). *Second*, it was not raised by plaintiff' in opposition to summary judgment, which is where arguments pertaining to whether there is a "trialworthy issue" must be asserted. *Wolford v. Landmark Am. Ins. Co.*, 196 W.Va. 528, 531, 474 S.E.2d 458, 4661 (1996) (per curiam) ("That contention, however, was not raised below in response to the motion for summary judgment ... . The appellant did not resist the motion ... for summary judgment and now asks this Court to reverse that judgment upon a contention advanced upon appeal for the first time... . [I]t is not properly before this Court."); *accord Wang-Yu Lin v. Shin Yi Lin*, 224 W.Va. 620, 625 n.7, 687 S.E.2d 403, 408 n.7 (2009) (per curiam).

action is a matter of substance governed, even in state courts, by federal decisional authority. *See, e.g.*, *CSX Transp., Inc. v. McBride*, 131 S. Ct. 2630, 2636 (2011); *Sorrell*, 549 U.S. at 168-69; *Rogers*, 352 U.S. at 506. Causation is "inseparably connected with the [FELA] right of action," and therefore must be "settled according to general principles of law as administered in the Federal courts." *See, e.g.*, *Monessen Sw. Ry. v. Morgan*, 486 U.S. 330, 335 (1988) (internal quotation marks omitted).

Federal case law uniformly holds that a FELA plaintiff who claims to have suffered injury as a result of exposure to a toxic substance must prove both general causation and specific causation.[15] *See, e.g.*, *Myers v. Ill. Cent. R.R.*, 629 F.3d 639, 642 (7th Cir. 2010) (affirming summary judgment in favor of railroad in FELA case because the plaintiff's "general causation testimony" was not "sufficient to survive summary judgment"); *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 350, 352 (5th Cir. 2007) (affirming summary judgment in favor of defendant in Jones Act case after concluding that the plaintiff's expert's "testimony regarding general causation" was unreliable and inadmissible)[16]; *Wills v. Amerada Hess Corp.*, 2002 WL 140542, at *1, *14 (S.D.N.Y. 2002) (granting summary judgment in FELA case and explaining that the "generally accepted methodology for

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[15] Plaintiff wrests out of context a statement in the Restatement (Third) of Torts that "'exposure,' 'general causation,' and 'specific causation' ... are not 'elements' of a plaintiff's cause of action," and "in *some cases* may not require separate proof." Plf. Br. 17 (quoting Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 28 cmt. c(1) (2010); emphasis added). But Restatement § 28 cmt. c makes clear that "[w]hen"—as here—"group-based statistical evidence is proffered in a case, ... the substance *must* be capable of causing the disease ('general causation') *and* that the substance must have caused the plaintiff's disease ('specific causation')." (Emphasis added.) Thus, the Restatement, consistent with the overwhelming weight of authority, confirms that without reliable evidence of general causation, a toxic-exposure plaintiff cannot prevail. *See, e.g.*, *City of Littleton v. Indus. Claim Appeals Office*, __ P.3d __, 2012 WL 5360912, at *2 & n.2 (Colo. Ct. App. 2012) ("[C]ourts traditionally evaluate the plaintiff's proof by examining two aspects of causation: general causation and specific causation," which are "analytical categories that courts use to evaluate proof of 'but for' causation.") (citing Restatement (Third) of Torts § 28 cmt. c(1)); *Ranes v. Adams Labs., Inc.*, 778 N.W.2d 677, 688 (Iowa 2010) ("We believe it is appropriate ... to use the bifurcated causation language in toxic-tort cases.") (citing Restatement (Third) of Torts § 28 cmt. c).

[16] *Knight* arose under the Jones Act, not FELA, but as noted by plaintiff, the statutes' causation standards are identical. Plf. Br. 10 n.8.

determining whether a person's illness was caused by a specific toxin" includes "establish[ing] that the toxin is capable of producing plaintiff's illness," which is "called 'general causation'").

It makes logical sense to analyze causation in a toxic-exposure case, as federal law does, sequentially in terms of general and specific causation. As noted above, general causation is whether a substance is *capable* of causing a particular disease in the general population, while specific causation is whether exposure to the substance *in fact* caused the particular plaintiff's disease. Unless a substance *could* in theory cause a disease, there is no basis for anyone—whether an expert or the ultimate factfinder[17]—to say that the substance *did* cause the plaintiff's condition. This is just common sense. Thus, "[s]equence matters: a plaintiff must establish general causation before moving to specific causation." *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 378 (5th Cir. 2010); *Knight*, 482 F.3d at 351 ("Evidence concerning specific causation in toxic tort cases is admissible only as a follow-up to admissible general-causation evidence."). Even the *King* case, upon which plaintiff relies extensively (*e.g.*, Plf. Br. 24-36), unequivocally states that:

> To prevail, a [FELA] plaintiff must show both general and specific causation. But a court should first consider whether a party has presented admissible general causation evidence before considering the issue of admissible specific causation evidence.

762 N.W.2d at 34.

In sum, contrary to plaintiff's contention, a FELA plaintiff who claims injury from exposure

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[17] Federal courts have also discussed general and specific causation in the context of what it takes for an expert to render a reliable causation opinion under *Daubert* principles, which the courts of this State generally apply and follow. *See* Plf. Br. 23 (recognizing that the *Wilt/Gentry* standard "'follows the general framework of the federal rules'") (quoting *Gentry*, 195 W.Va. at 525, 466 S.E.2d at 184). Courts have uniformly explained that before "ruling out" alternative causes and arriving at a reliable specific-causation opinion, the expert must first reliably "rule in" possible causes—and this requires that "the expert's opinion on general causation [be] 'derived from [a] scientifically valid methodology.'" *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1195 (11th Cir. 2010); *see also Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 678-79 (6th Cir. 2011); *Myers*, 629 F.3d at 644; *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1252-55 (11th Cir. 2005); *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005); *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1058 (9th Cir. 2003); *Raynor*, 104 F.3d at 1376; *Norris*, 397 F.3d at 885.

to a toxic substance must present admissible evidence of general causation in order to recover under the governing federal standard. The circuit court excluded all of plaintiff's general-causation experts. There was, therefore, no genuine issue of material fact as to FELA's requisite causation element. And because plaintiff "failed to make a sufficient showing on an essential element of the case that [she] ha[d] the burden to prove," summary judgment was appropriately entered in favor of CSXT. Syl. pt. 4, *Painter*, 192 W.Va. 189, 451 S.E.2d 755.

III. THE CIRCUIT COURT DID NOT ABUSE ITS DISCRETION IN EXCLUDING PLAINTIFF'S EXPERT TESTIMONY AS UNRELIABLE.

Plaintiff's third assignment of error challenges the circuit court's discretionary judgment that the testimony of her general causation experts was unreliable under the *Wilt/Gentry/Daubert* standard and thus inadmissible. Consistent with this Court's suggestion in *San Francisco*, the circuit court held an evidentiary hearing at which both parties' experts were heard. On the basis of this developed factual record, the circuit court found that plaintiff's experts had not applied reliable scientific methodology and that their opinions were not reliably grounded in the studies on which they purported to rely. That determination is not only unassailable under the abuse-of-discretion standard of review, but clearly correct and in accord with case law elsewhere.

A. The Circuit Court Correctly Identified The Relevant Causation Issue.

As explained *infra* (at pp. 27-28), general causation addresses whether a particular substance is, at a given level of exposure, *capable* of causing a certain disease in the general population. The circuit court correctly identified the general causation question relevant here: whether exposure to railroad diesel exhaust can cause multiple myeloma. *E.g.*, App. 777, 783, 796, 802; *see* App. 110 (Infante), 467 (Durie). It is irrelevant whether other (or unspecified) kinds of exhaust can cause other (or unspecified) kinds of cancer. Cancers are "substantially different" from one another, and many chemicals are known to cause certain types of cancer, but not others. App. 174-175 (Shields). For example, although cigarette smoke can cause many types of lung cancer, everyone—both

plaintiffs' experts and CSXT's experts—agrees that it *cannot* cause multiple myeloma. App. 479 (Durie); *see also* App. 175, 217 (Shields), 493 (Green). A general causation opinion must therefore be targeted to both the substance and the disease.[18]

B. The Circuit Court Correctly Found That The Methodology Used By Plaintiff's Experts Did Not Satisfy The *Wilt/Gentry/Daubert* Reliability Standard.

Plaintiff complains that the circuit court supposedly "overemphasized" various defects in her experts' methodology and, in so doing, purportedly "usurped" the jury's role by requiring the experts' causation opinions to be not only reliable, but correct. Plf. Br. 20, 24. Plaintiff necessarily contends that the circuit court was *required* to conclude that her experts' testimony was reliable, and that the court therefore necessarily abused its discretion by excluding them, even though—as the circuit court found—her experts relied on epidemiological studies that did not produce statistically significant findings (*id.* at 25-27); relied on studies that did not exhibit a dose-response correlation (*id.* at 33); cherry-picked supportive results (*id.* at 28-29); and relied on an animal study that was not comparable to Harris's own exposure (*id.* at 30-31).[19] That is plainly not the law.

A trial court has the discretion to exclude an expert opinion that is not sufficiently tied to reliable underlying data. *See, e.g., Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Indeed, "when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* ... *mandate[s]* the exclusion of that unreliable opinion testimony."

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[18] Although plaintiff at times appears to accept this proposition (*see, e.g.*, Plf. Br. 19, 25), she often poses the causation inquiry at a meaninglessly high level of generality. Suffice it to say, it is irrelevant that diesel exhaust may "cause[] cancer in general" or that it may contain components that are "probable human carcinogen[s]." *E.g., id.* at 3-6. Studies that address substances other than railroad diesel exhaust or diseases other than multiple myeloma cannot be the basis for a reliable causation opinion in this case, where it is alleged that railroad diesel exhaust caused multiple myeloma.

[19] Plaintiff asserts in passing that the circuit court's findings credited the testimony of CSXT's witnesses over the "contrary testimony" of her experts. Plf. Br. 28 n.18. But the circuit court was plainly entitled to make such a discretionary call, and this Court "will not disturb a circuit court's decision unless the circuit court makes a clear error of judgment or exceeds the bounds of permissible choices in the circumstances." *Gribben*, 195 W.Va. at 500, 466 S.E.2d at 159.

Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 266 (2d Cir. 2002) (emphasis added). But, in seeking to compel the admission of her experts' testimony, plaintiff effectively seeks a *per se* rule that any general causation expert who purports to rely on epidemiological or animal studies, *must* be allowed to testify under the *Wilt/Gentry/Daubert* standard, no matter how incomplete, inconclusive, or inapposite those studies may be. This Court's precedent is squarely to the contrary: "'[N]othing in the Rules [of Evidence] appears to have been intended to permit experts to speculate in fashions unsupported" by "reliable ... data.'" *Gentry*, 195 W.Va. at 527-28, 466 S.E.2d at 186-87.

Nowhere in her opening brief does plaintiff directly confront the circuit court's analysis and even attempt to explain why *her experts'* opinions were reliable notwithstanding the *specific* methodological defects identified by the circuit court. The many cases excluding experts for the same reasons cited by the circuit court confirm that exclusion of plaintiff's experts in this case reflected a routine, reasoned exercise of discretion.

1. Trial courts have discretion to exclude causation opinions that are not reliably derived from relevant epidemiological studies.

The circuit court carefully scrutinized the epidemiological studies cited by plaintiff's experts. The results in some lacked statistical significance and thus, as the court recognized, could have been the result of random chance. App. 778-779. Of the studies that did have statistically significant results, the circuit court found that many did not examine the particular substance to which Harris had been exposed, railroad diesel exhaust. App. 785-788; *see supra* pp. 8-9 (discussing, *inter alia*, the Sonoda article, Infante's meta-analysis, and the Hansen, Doll, Semenciw, and Smith studies). And of those that did examine diesel exhaust in particular, many reached only tentative or speculative conclusions, finding a potential "link" or calling for additional inquiry. App. 786; *see supra* pp. 8-9 (discussing, *inter alia*, IARC Technical Publication 42, the Lee article, and the Sjogren letter). Yet other studies, the court found, merely summarized existing studies without further analysis. App. 786-787; *see supra* pp. 8-9 (discussing, *inter alia*, the Schottenfeld treatise and IARC Technical

Publication 42).

In analyzing the proffered bases for the opinions of plaintiff's experts and concluding that they "were not sufficient, whether individually or in combination, to support their conclusions," the circuit court faithfully applied the *Daubert* reliability test. *Joiner*, 522 U.S. at 146-47. As the U.S. Supreme Court has explained, when experts rely upon studies predicated on facts "dissimilar to the facts presented in [the] litigation," the trial court "may conclude that there is simply too great an analytical gap between the data and the opinion proffered" and "reject[] the experts' reliance on them." *Id.* at 144-46; *Wells*, 601 F.3d at 380-81 (rejecting expert's reliance on literature that "does not provide the necessary 'scientific knowledge' upon which to base an opinion under *Daubert*"); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010) (requiring exclusion of expert because there were too many "speculative jumps" in his reasoning between the underlying data and his opinions).

Other appellate courts—including the U.S. Supreme Court—have affirmed the exclusion, or reversed the admission, of expert testimony based on the same methodological "gaps" identified by the circuit court here:

- Lack of statistical significance: *See, e.g.*, *Joiner*, 522 U.S. at 145 (rejecting expert's reliance on study that found somewhat higher "incidence of lung cancer deaths" because the "increase ... was not statistically significant"); *Wells*, 601 F.3d at 380 ("this court has frowned on causative conclusions bereft of statistically significant epidemiological support"); *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001) (per curiam) (discounting opinion because "the paucity of examples presented statistically insignificant results"); *In re TMI Litig.*, 193 F.3d 613 (3d Cir. 1999); *Brock v. Merrell Dow Pharm., Inc.*, 874 F.2d 307, 312 (5th Cir. 1989).[20]

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[20] For the contrary proposition, plaintiff cites *Berry v. CSX Transp., Inc.*, 709 So. 2d 552 (Fla. Dist. Ct. App. 1998), and *Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996). Plf. Br. 26-27. But *Berry* applied the *Frye* standard rather than the *Daubert* standard and, moreover, was considering the matter on *de novo* review. 709 So. 2d at 556-57. Neither is applicable here. *See supra* pp. 17-18. And a subsequent D.C. Circuit decision emphasized that *Ambrosini* does *not* stand for the proposition that a "conclusory assertion of some lower threshold of statistical significance" could suffice and compel admission of expert testimony, because the judge "must make [an] *independent* inquiry regarding reasonableness of reliance" on the studies at issue. *Raynor*, 104 F.3d at 1374 (emphasis added).

- Reliance on studies that lump together different types of exhaust or different chemicals altogether: Engine exhaust—even diesel engine exhaust—does not have uniform characteristics. App. 65-66 (Goldstein), 136-150 (Infante); *see supra* pp. 4 n.3, 8. Thus, the circuit court properly rejected reliance on studies that did not specifically address railroad diesel engine exhaust. *See, e.g., Joiner*, 522 U.S. at 145-46 (study grouping "expos[ures] to numerous potential carcinogens" was "of no help"); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1246 (11th Cir. 2005) (improper to assume "the same effect by [substances] in the same class," which is a "presumption[] [that] do[es] not make for reliable opinions"); *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 782 (10th Cir. 1999) (trial court permissibly excluded opinion resting on premise that defendant's products are "chemically similar" to substance found to cause leukemia); *Gideon v. Johns-Manville Sales Corp.*, 761 F.2d 1129, 1145 (5th Cir. 1985) ("all asbestos-containing products cannot be lumped together").

- Reliance on studies for propositions that the studies' authors themselves were unwilling to embrace: *See, e.g., Joiner*, 522 U.S. at 145 (given that the authors were "unwilling to say that PCB exposure had caused cancer among the workers they examined, their study did not support the experts' conclusion that [the plaintiff's] exposure to PCB's caused his cancer"); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 278 (5th Cir. 1998) (discounting article whose "authors made it clear that their conclusions were speculative because of the limitations of the study").

- Reliance on sources that merely summarize other studies: A review that simply catalogues existing literature cannot be more reliable support for a causation opinion than the studies underlying it. *See, e.g., Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 (8th Cir. 2000); *Moore*, 151 F.3d at 278.

In short, the circuit court properly employed the *Daubert* reliability test "to assess whether a particular conclusion may be reliably drawn from the evidence." *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010). "[N]othing in ... *Daubert* ... requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146; *see also Gentry*, 195 W.Va. at 527-28, 466 S.E.2d at 186-87. Because the opening brief does not even *attempt* to defend or justify the leap between the studies *in this case* and the conclusions of plaintiff's experts, the circuit court's exclusion of those experts should be affirmed.

2. Trial courts have discretion to exclude causation opinions that fail to account for the dose-response principle.

Dose-response is the "very powerful" notion that when a substance is capable of causing a disease, "the more exposure you have, the higher is the risk." App. 95 (Infante), 184 (Shields). When

there is no dose-response—*i.e.*, when higher exposures do *not* lead to higher risks—it is a strong indication that the purported causal association stands on shaky and unreliable ground. App. 177, 184-185 (Shields); *see supra* pp. 7, 12. "[T]he link between an expert's opinions and the dose-response relationship is a *key* element of reliability in toxic tort cases" (*McClain*, 401 F.3d at 1241 n.6 (emphasis added)), and thus, an "expert who avoids or neglects [the dose-response] principle ... casts suspicion on the *reliability* of his methodology." *Id.* at 1242 (citing papers issued by the Federal Judicial Center; emphasis added); *see also Kilpatrick*, 613 F.3d at 1339 (same); *Newman v. Motorola, Inc.*, 78 F. App'x 292, 294 (4th Cir. 2003) (per curiam) (concluding that research was unreliable because it "failed to demonstrate a dose-response relationship").

Here, the circuit court found, and plaintiff does not dispute, that (1) cigarette smoke contains the same carcinogenic components (*i.e.*, benzene, PAHs, and pristane) allegedly found as diesel exhaust but in even *higher* doses, and (2) cigarette smoke can reach the bone marrow, where multiple myeloma develops, *yet* (3) cigarette smoke does *not* cause multiple myeloma at all. *E.g.*, App. 780-783 (citing, *inter alia*, App. 52 (Goldstein), 169-170, 217-219 (Shields), 478-479 (Durie), 487 (Green)); *see supra* pp. 7, 12. In other words, multiple myeloma does *not* exhibit a dose-response to the purported chemical components of diesel exhaust.

Plaintiff dismisses this entire line of reasoning as mere "cross-examination fodder." Plf. Br. 32. But the absence of a dose-response to the constituents of diesel exhaust that purportedly can cause multiple myeloma—and the complete failure of plaintiff's experts to explain how their causation opinions could possibly be squared with it—go to the very heart of the reliability of the methodology employed by plaintiff's experts. The circuit court properly concluded that plaintiff's experts' failure to account for the lack of a dose-response undermined their opinions' reliability.

3. Trial courts have discretion to exclude causation opinions that rely on animal studies based on exposures not comparable to those at issue.

The circuit court found—and this, again, is undisputed—that there are no studies in which

animals exposed to diesel exhaust developed the disease at issue here, multiple myeloma. *E.g.*, App. 802; *see also* App. 62-64, 67 (Goldstein), 474 (Durie); *see supra* pp. 3-4. Plaintiff's animal toxicologist, Goldstein, could not "direct [the Court] to a single animal study or an animal that developed multiple myeloma" from an exposure like Harris's. App. 63-64 (Goldstein). Not only did the Potter and Van Den Eeden studies, on which he and plaintiff's other experts relied, involve mice that had been exposed to different chemicals (pristane and coal tar, respectively) via different exposure routes (injection and ingestion, respectively), but the mice did not even develop multiple myeloma (only plasmacytomas and chromosomal changes, respectively). *See supra* pp. 4-5.

Like the plaintiff in *Joiner*, plaintiff here does not "explain[] how and why [her] experts could have extrapolated their opinions from these seemingly far-removed animal studies," and instead proceeds "as if the only issue [was] whether animal studies can *ever* be a proper foundation for an expert's opinion." 522 U.S. at 144 (emphasis added; internal quotation marks omitted); *cf.* Plf. Br. 30-32. In *Joiner*, the U.S. Supreme Court readily rejected the plaintiff's attempt to change the topic, and this Court should as well: "Of course, whether animal studies can ever be a proper foundation for an expert's opinion was not the issue. The issue was whether *these experts' opinions* were sufficiently supported by the animal studies on which they purported to rely." *Joiner*, 522 U.S. at 144.

And here as in *Joiner*, the animal "studies were so dissimilar to the facts presented in this litigation that it was not an abuse of discretion for the [trial court] to have rejected the experts' reliance on them." 522 U.S. at 144-45; *see also id.* at 144 (rejecting reliance on study where substance, to which the plaintiff was only topically exposed, was "injected into the mice" and the mice developed a different form of cancer); *Wills*, 379 F.3d at 39 (rejecting reliance on studies in which "rats ingested" benzene and "there was no suggestion that decedent ingested benzene"); *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996) (study regarding "hematopoietic cancers ... is not probative on the causation of brain cancer"). The circuit court correctly determined that the Potter

and Van Den Eeden studies did not provide a sufficient basis for the opinions of plaintiff's experts.

4. Trial courts have discretion to exclude causation opinions that do not reflect the "same level of intellectual rigor that characterizes the practice of an expert in the relevant field."

In excluding plaintiff's experts, the circuit court also properly considered the fact that their litigation opinions were, at the very least, in tension with the methodology and conclusions reflected in their other professional or scholarly work. For example, although Durie's testimony was that diesel exhaust causes multiple myeloma, that opinion is not found in his own published writing on the causes of multiple myeloma or on the website of the International Myeloma Foundation, which he chairs. App. 773-774; *see supra* p. 12. And although Infante recognized that a thorough and comprehensive evaluation of the literature is necessary to arrive at a trustworthy causation opinion (App. 83, 105-106), and denied cherry-picking studies in this case (App. 108-109), in reaching his litigation opinion he failed to consider the EPA's Health Assessment document on diesel exhaust, failed to include the directly relevant Boffetta 2001 paper in his meta-analysis, and failed to reconcile his opinion with the mass of contrary epidemiological studies. App. 792-793; *see supra* pp. 9-10.

As plaintiff elsewhere acknowledges, the "very purpose" of the *Daubert* reliability inquiry is to "'make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the *same level of intellectual rigor* that characterizes the practice of an expert in the relevant field.'" Plf. Br. 22 (indirectly quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); emphasis added). The circuit court correctly considered this factor when analyzing the reliability of the methodology employed by plaintiff's experts.

5. The decision below can be affirmed on the alternative ground that there was no basis upon which Harris's exposure to diesel exhaust could be compared with the exposures examined in the studies.

Finally, this Court can affirm the circuit court's decision based on the undisputed fact that none of the studies on which plaintiff's experts relied ever determined the minimum *amount* of diesel

exhaust that is allegedly necessary to cause cancer in human beings. App. 150 (Infante: "no one ever measured it"). This lacuna—and the absence of any evidence regarding Harris's own level of exposure to diesel exhaust while employed by CSXT beyond vague testimony about how often Harris and his co-workers would, on occasion, smell diesel exhaust during their runs (App. 393-394)—is fatal to plaintiff's case because a plaintiff in a "toxic-tort case must prove the levels of exposure that are hazardous to human beings generally, as well as the plaintiff's actual level of exposure to the defendant's toxic substance." *Richardson*, 2011 WL 4477791, at *19.

This makes sense—and it reflects the fundamental tenet of toxicology that "the dose makes the poison"—because a low-level exposure to an otherwise harmful substance might pose no health risk at all. App. 177; *see also Allen*, 102 F.3d at 199 ("[s]cientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary" to reliably establish causation); *accord Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 678-79 (6th Cir. 2011); *Fuesting v. Zimmer, Inc.*, 421 F.3d 528, 536 (7th Cir. 2005), *modified on rehearing*, 448 F.3d 936 (7th Cir. 2006); *McClain*, 401 F.3d at 1242; *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1106-07 (8th Cir. 1996); *Mancuso v. Consol. Edison Co. of N.Y., Inc.*, 967 F. Supp. 1437, 1445, 1453 (S.D.N.Y. 1997); *see also Tolley v. ACF Indus., Inc.*, 212 W.Va. 548, 559, 575 S.E.2d 158, 169 (2002) ("Critical to establishing exposure to a toxic chemical is knowledge of the *dose or exposure amount* and the duration of the exposure.") (emphasis added).[21]

The dearth of data identifying the hazardous level of railroad diesel exhaust, coupled with

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[21] Plaintiff also asserts that the substantive tort law of West Virginia does not require a toxic-tort plaintiff to establish his or her level of exposure in order to recover. Plf. Br. 35-36. That is both irrelevant and incorrect. It is irrelevant because this case is governed by federal standards (to wit, the FELA causation standard and the *Daubert* reliability standard adopted by this Court in *Gentry* and *Wilt*), and they *do* place a paramount importance on dose. It is in any event incorrect because this Court in *Tolley* expressly recognized that a "critical factor in determining whether [an] employee was exposed to unsafe working condition is evidence of *intensity* of exposure to chemicals or *concentration levels*." 212 W.Va. at 559, 575 S.E.2d at 169 (emphasis added).

the absence of meaningful information about Harris's exposures, means that plaintiff's experts could not reliably opine as to general causation, and is an independent basis for affirmance.[22]

* * *

As a parting shot, the opening brief suggests that the circuit court should have been required to find plaintiff's experts admissible because they purported to employ a "weight of the evidence" methodology that supposedly took into account all relevant scientific evidence in order to reach a causal conclusion. *E.g.*, Plf. Br. 4 n.6, 36-37 (citing, *inter alia*, *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11 (1st Cir. 2011), *cert. denied*, 132 S. Ct. 1002 (2012)). But even the *Milward* opinion stresses that "weight of the evidence" is not a phrase with talismanic effect; "admissibility must turn on the particular facts of the case," and exclusion on *Daubert* grounds is required when an expert's "specific theory [does] not have sufficient scientific support" and is "at best weakly supported, if not contradicted, by the evidence." 639 F.3d at 19 & n.9 (internal quotation marks omitted). Indeed, in *Joiner* itself, the plaintiff's experts relied on a "weight of the evidence" approach to support that causation conclusion (522 U.S. at 152-53 & n.4 (Stevens, J., concurring in part and dissenting in part)), and the U.S. Supreme Court nonetheless affirmed their exclusion on *Daubert* grounds. The *Joiner* court concluded that the trial court had discretion to reject an opinion based on studies that "were not sufficient, whether individually or in combination, to support [the experts'] conclusions." *Id.* at 146-47. And that was the case here. The decision below should, accordingly, be affirmed.

C. The Circuit Court's Exclusion Of Plaintiff's Experts Is In Accord With The Better-Reasoned Authority In This Precise Context.

Assessing the reliability of an expert's methodology requires a fact-intensive inquiry. That, among other reasons, is why the circuit court is afforded significant discretion to make that

[22] Plaintiff notes that this issue was not raised below. Plf. Br. 36. But "[t]his Court may ... affirm the judgment of the lower court when it appears that such judgment is correct on any legal ground disclosed by the record, regardless of the ground, reason or theory assigned by the lower court as the basis for its judgment." Syl. pt. 3, *Barnett v. Wolfolk*, 149 W.Va. 246, 140 S.E.2d 466 (1965).

determination based on the precise circumstances before it. *See supra* pp. 17-18. But it bears noting that the circuit court's decision in this case is consistent with the weight of authority addressing whether putative experts can reliably opine that exposure to diesel exhaust causes multiple myeloma. Appellate courts in Arkansas and Texas have excluded causation experts on *Daubert* grounds, and their reasoning is instructive insofar as plaintiff's experts in this case committed many of the same methodological errors and relied upon many of the same deficient sources identified in those cases.

In *Navarro*, for example, the Court of Appeals of Texas concluded that "the opinions of the three causation expert[s]"—who relied upon the 1989 Boffetta and the Hansen studies—were "based on flawed methodology." 90 S.W.3d at 757. "The author of the Boffetta study noted that because there were only three railroad worker deaths from multiple myeloma in the study, there was no statistical significance between railroad workers and multiple myeloma." *Id.* Moreover, it was "impossible to tell whether any or all of the three railroad workers who developed multiple myeloma were even exposed to diesel exhaust." *Id.* As for the Hansen study, its author "refused to find that exposure to diesel exhaust causes multiple myeloma" and posited that the findings "may have been due to chance." *Id.* And in *Richardson*, the Arkansas Court of Appeals affirmed the exclusion of the experts based on the serious flaws in their methodology and the absence of support for their opinions in the articles and studies upon which they purported to rely. 2011 WL 4477791, at *23. Like plaintiff's experts here, the experts in *Richardson* cited, *inter alia*, a meta-analysis that Infante had performed, the 1989 Boffetta study, and the Hansen study. *Id.* at *10-12, *23. Their reliance on these sources was unavailing:

> Dr. Brautbar's [*i.e.*, the plaintiff's expert's] reliance on Infante's study was misplaced, in view of the fact that it analyzed chemical workers, not railroad employees, with direct exposure to nearly-pure benzene. Dr. Brautbar's reliance on the Boffetta study was also misplaced, as the study's author did not conclude that diesel exhaust caused multiple myeloma. He did not explain the limitations of the Flodin study and its author's recognition of those limitations. The Hansen study, on which Dr. Brautbar also relied, was expressly rejected in *Navarro*... . Dr. Brautbar ignored studies that did not support his opinion.

Id. at *23.

Plaintiff tries to brush aside this contrary authority, asserting that it should be given little weight because "Arkansas law[] ... differs substantially from West Virginia law." Plf. Br. 35. But that is irrelevant, because this case is governed by the *federal* law—the substantive law of FELA causation and the *Daubert* reliability standard endorsed by this Court in *Gentry*. *See supra* pp. 26-29. Plaintiff also tries to avoid the contrary authority on the ground that this case is subject to *de novo* review. Plf. Br. 36. But that is incorrect. Although the *legal standards* for evaluating the admissibility and reliability of expert testimony are reviewed *de novo* (*San Francisco*, 221 W.Va. at 740, 656 S.E.2d at 491)—and the circuit court did not err in this regard (*see supra* at pp. 20-24)—whether the circuit court properly applied those standards to the *facts of a specific case* is reviewed for an abuse of discretion, as is the circuit court's ultimate "ruling with respect to the admissibility of expert testimony." *Ferguson*, 222 W.Va. at 77, 662 S.E.2d at 519; *see supra* pp. 17-19.

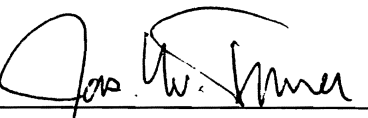
Plaintiff thus is left to rely on the Nebraska Supreme Court's opinion in *King*. Plf. Br. 33-35. But this Court should—like the Arkansas court in *Richardson*—"decline to adopt" *King*, which is "not in accord with federal precedent" on the *Daubert* reliability standard. *Richardson*, 2011 WL 4477791, at *13, *19; *cf. supra* p. 22 n.11. Regardless, *King* does not help plaintiff overcome the circuit court's discretionary ruling in this case. *King* makes clear that a trial court may "consider[] as part of its reliability inquiry whether an expert has cherry-picked a couple of supporting studies," and "has discretion to exclude expert testimony if there is simply too great an analytical gap between the data and the opinion proffered." *Id.* at *King*, 762 N.W.2d at 43, 48 (internal quotation marks omitted). That is precisely what the circuit court did here.

CONCLUSION

The judgment of the circuit court should be affirmed.

CSX TRANSPORTATION, INC.,

DATED: February 4, 2013

By: 

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CERTIFICATE OF SERVICE

I hereby certify that I have, on this the 4th day of February 2013, sent via First Class Mail the foregoing **RESPONDENT'S BRIEF** upon all counsel of record in this cause, whose names and addresses are as follows:

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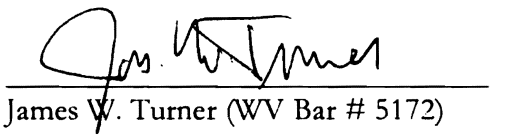

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