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SUPREME COURT OF APPEALS
OF WEST VIRGINIA

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

DOCKET NO. 12-1135

DEBORAH KAY HARRIS,
Administratrix of the Estate
of Ronald K. Harris, deceased,
Petitioner

V.)

CSX TRANSPORTATION INC.,
Individually and as successor in interest to
THE CHESSIE SYSTEM, INC.,
THE BALTIMORE & OHIO RAILROAD,
and THE CHESAPEAK & OHIO RAILWAY,
Respondent

Appeal from a final order of
the Circuit Court of Marshall County
(08-C-171M)

Petitioner's Brief

Counsel for Petitioner, Deborah Kay Harris

R. Dean Hartley (WV Bar # 1619)
Counsel of Record
Julie R. Magers (WV Bar # 10657)
J. Michael Prascik (WV Bar # 9135)
HARTLEY & O'BRIEN, P.L.L.C
2001 Main Street, Suite 600
Wheeling, West Virginia 26003
(304) 233-0777
dhartley@hartleyobrien.com

TABLE OF CONTENTS

ASSIGNMENTS OF ERROR 1

STATEMENT OF THE CASE 1

I. Dr. Peter Infante's Methodology 3

II. Dr. Lawrence Goldstein's Methodology 4

III. Dr. Brian G.M. Durie's Methodology 5

IV. The Trial Court Excluded Each of Petitioner's Experts 6

SUMMARY OF ARGUMENT 7

STATEMENT REGARDING ORAL ARGUMENT AND DECISION 7

STANDARD OF REVIEW 8

ARGUMENT 8

I. The Liberal Standard of Causation Applicable Under the Federal Employers' Liability Act, 45 U.S.C. § 51, *et seq.*, Affects a Trial Court's *Daubert/Wilt* Analysis Under Rule 702, W.Va. R. Evid.] 8

II. West Virginia Law Does Not Require a Toxic Tort Plaintiff to Prove General Causation (That Diesel Exhaust Causes Multiple Myeloma) Before Her Expert Witnesses Are Permitted to Testify in a Toxic Tort Case 16

III. Even Assuming That the FELA Standard of Causation Has No Impact on a *Daubert/Wilt* Analysis, and That Petitioner Was Required to Establish General Causation, Petitioner's Expert Witnesses' Methodology Met the Legal Requirements to Render Their Testimony Admissible, and a Jury Should Have Been Permitted to Decide the Ultimate Issue of Causation . . . 20

A. The Petitioner's Expert Witnesses' Methodology Was Reliable 23

1. Trial Court's Findings Regarding Epidemiologic Studies . . . 24

2. Trial court's findings regarding the applicability of animal studies 30

3. Cross-examination fodder 32

B. Other Courts Have Rejected the Analysis Utilized by the Trial Court 33

C. Petitioner's Expert Witnesses' "Weight-of-the-Evidence" Approach 36

CONCLUSION 38

TABLE OF AUTHORITIES

CASELAW

Ambrosini v. Labarraque, 101 F.3d 129 (D.C. Cir. 1996) 26

Avery v. Grand Trunk Western Railroad, 2011 Mich. App. LEXIS 1113 (2011) 12-13

Berry v. CSX Transp., 709 So. 2d 552 (Fla. Dist. Ct. App. 1st Dist. 1998) 26-27

Bitler v. A.O. Smith Corp., 391 F.3d 1114 (10th Cir. 2004) 4, 21

Bloomquist v. Wapello County, 500 N.W.2d 1 (Iowa 1993) 27

Boeing Co. v. Shipman, 411 F.2d 366 (5th Cir. 1969) 11

Bourjaily v. United States, 483 U.S. 171, 107 S. Ct. 2775, 97 L. Ed. 2d 144 (1987) 21

Brock v. Merrell Dow Pharm., Inc., 874 F.2d 307 (5th Cir. 1989) 26

Chavers v. GMC, 79 S.W.3d 361 (Ark. 2002) 35

Claar v. Burlington Northern R.R. Co., 29 F.3d 499 (9th Cir. 1994) 15

Cook v. Rockwell International Corporation, 580 F. Supp. 2d 1071 (D. Colo. 2006) 25

Consolidated Rail Corp. v. Gottshall, 512 U.S. 532, 114 S. Ct. 2396, 129 L. Ed. 2d 427 (1994) 8

Crane & Equip. Rental Co. v. Park Corp., 177 W. Va. 65, 350 S.E.2d 692 (1986) 18

Crookham v. New York Cent. R.R. Co., 144 W. Va. 196, 107 S.E.2d 516 (1959) 9, 15

CSX Transp., Inc. v. McBride, 564 U.S. ___, 131 S.Ct. 2630 (2012) 8

Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 113 S.Ct. 2786,
125 L.Ed.2d 469 (1993) 2, 11, 21, 32

Donaldson v. Central Illinois Public Service Co., 199 Ill. 2d 63, 90-91, 767 N.E. 2d 314, 331-
332 (2002) 18-19

Epp v. Lauby, 271 Neb. 640, 715 N.W.2d 501 (2006) 34-35

Gallick v. Baltimore and Ohio R. Co., 372 U.S. 108 (1963) 10

Gardner v. CSX Transp., 201 W. Va. 490, 498 S.E.2d 473 (1997) 9, 17

Gates v. Texaco, Inc., 2008 Del. Super. LEXIS 441 (Del. Super. Ct. Mar. 20, 2008) 17

Gentry v. Mangum, 195 W.Va. 512, 466 S.E.2d 171 (1995) 22, 23, 32

Heller v. Shaw Indus., Inc., 167 F.3d 146 (3d Cir. 1999) 27

Hines v. Consolidated Rail Corp., 926 F.2d 262 (3d. Cir. 1991) 11

Hopkins v. Dow Corning Corning, 33 F.3d 1116 (9th Cir. 1994) 24

In re Ephedra Prod. Liab. Litig., 393 F. Supp.2d 181 (S.D.N.Y. 2005) 27

In re Flood Litig. Coal River Watershed, 222 W.Va. 574, 668 S.E.2d 203 (2008) 8, 36

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Jenkins v. CSX Transportation, Inc., 220 W.Va. 721, 649 S.E.2d 294 (2007) 15, 17-19

Joiner v. General Electric Company, 78 F.3d 524 (11th Cir. 1996) 23

King v. Burlington Northern Santa Fe Railway Company, 277 Neb. 203,
762 N.W. 2d 24 (2009) 24-26, 29, 33, 34, 35

Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999) 22

Lavender v. Kurn, 327 U.S. 645, 653 (1946) 10

Leake v. U.S., 843 F. Supp.2d 554 (E.D. Pa. 2011) 31

Magistrini v. One Hour Martinizing Dry Cleaning, 180 F.Supp. 2d 584 (D.N.J. 2002) 21

McClellan v. I-Flow Corp., 710 F. Supp.2d 1092 (D. Ore. 2010) 31

McGraw v. Norfolk & W. Ry., 201 W. Va. 675 (W. Va. 1997) 9

Metabolife Int'l, Inc. v. Wornick, 264 F.3d 832 (9th Cir. 2001) 31

Milward v. Acuity Specialty Prods. Group, Inc., 639 F.3d 11 (1st Cir. 2011)4, 5, 21, 22, 27, 30, 37

Painter v. Peavy, 192 W.Va. 198, 451 S.E.2d 755 (1994) 8

Perry v. Melton, 171 W. Va. 397, 299 S.E.2d 8 (1982) 18

Pygman v. Helton, 148 W.Va. 281, 134 S.E.2d 717 (1964) 18, 20

Richardson v. Union Pacific R.R. Co., 2011 Ark. App. LEXIS 602 (Ark. Ct. App. 2011) . . 35-36

Rider v. Sandoz Pharm. Corp., 295 F.3d 1194 (11th Cir. 2002) 27

Rogers v. Missouri Pacific Railroad Co., 352 U.S. 500, 77 S. Ct. 443,
1 L. Ed. 2d 493 (1957) 8, 9, 12, 15

San Francisco v. Wendy's Intern., Inc., 221 W.Va. 734, 656 S.E.2d 485 (2007) 8, 18, 22, 23

Savage v. Union Pacific Railroad Company, 67 F. Supp. 2d 1021 (E.D. Ark. 1999) 10, 14

Sexton v. Grieco, 216 W. Va. 714, 613 S.E.2d 81 (2005) 18

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State v. Thomas, 187 W.Va. 686, 691, 421 S.E.2d 227 (1992) 32

Taylor v. Union Pac. R.R. Co., 2010 U.S. Dist. LEXIS 96802 * 11 (S.D. Ill. Sept. 16, 2010) . . 14

Tiller v. Atlantic C. L. R. Co., 318 U.S. 54 (1943) 9

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U.S. v. Downing, 753 F.2d 1224 (3rd Cir. 1985) 24

U.S. v. Mitchell, 365 F.3d 215 (3rd Cir. 2004) 21

Walden v. Illinois Cent. Gulf R.R., 975 F.2d 361 (7th Cir. 1992) 9-10

Walker v. Sharma, 221 W.Va. 559, 564 S.E.2d 775 (2007) 23, 38

West Virginia Division of Highways v. Cutlip, No. 050404, April 17, 2006 20

Wills v. Amerada Hess Corp., 379 F.3d 32 (2nd Cir. 2004) 10-11

Wilt v. Buracker, 191 W.Va. 39, 443 S.E.2d 196 (1993) 2, 21, 22

STATUTES AND REGULATIONS

Cal. Rules of Court 8.1115(a) 13

Federal Employers' Liability Act (FELA), 45 U.S.C. § 51, *et seq.* 1

Jones Act, 46 U.S.C. app. §§ 688, *et seq.* 10

Locomotive Inspection Act, 49 U.S.C. § 20701 *et seq.* 1

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ASSIGNMENTS OF ERROR

1. THE TRIAL COURT FAILED TO CONSIDER THE LIBERAL STANDARD OF CAUSATION APPLICABLE UNDER THE FEDERAL EMPLOYERS' LIABILITY ACT, 45 U.S.C. § 51, *et seq.*, AND ITS IMPACT ON THE *DAUBERT/WILT* ANALYSIS UNDER RULE 702, W.VA. R. EVID.

2. THE TRIAL COURT REQUIRED PETITIONER TO PROVE GENERAL CAUSATION (THAT DIESEL EXHAUST **CAUSES** MULTIPLE MYELOMA) BEFORE HER EXPERT WITNESSES WOULD BE PERMITTED TO TESTIFY AS TO CAUSATION IN THIS TOXIC TORT CASE.

3. EVEN ASSUMING THAT PETITIONER WAS REQUIRED TO ESTABLISH GENERAL CAUSATION, THE TRIAL COURT FAILED TO APPROPRIATELY ANALYZE PETITIONER'S EXPERT WITNESSES' METHODOLOGY, AND INSTEAD SUBSTITUTED ITS OWN CONCLUSION ON THE ULTIMATE JURY ISSUE OF CAUSATION.

STATEMENT OF THE CASE

Ronald K. Harris filed the underlying civil action pursuant to the Federal Employers' Liability Act (FELA), 45 U.S.C. § 51, *et seq.* and the Locomotive Inspection Act, 49 U.S.C. § 20701 *et seq.* (hereinafter included in FELA) against his employer CSX Transportation, Inc. (hereinafter "CSX" or "respondent") in the Circuit Court of Marshall County, West Virginia, alleging that his exposure to diesel exhaust while employed by CSX caused his development of multiple myeloma[1]. During the pendency of the action, Mr. Harris died as a result of his multiple myeloma. Deborah Kay Harris, Administratrix of the Estate of Ronald K. Harris (hereinafter

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[1]Multiple myeloma is a cancer formed by malignant plasma cells mainly found in the bone marrow. When plasma cells become cancerous and grow out of control, they can produce a tumor called a plasmacytoma. If there is only a single plasma cell tumor, it is called an isolated (or solitary) plasmacytoma. When there is more than one plasma cell tumor, it is called multiple myeloma. *See* American Cancer Society Webpage, "What is Multiple Myeloma?" http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma. Last Visited, December 10, 2012. *See also*, Durie testimony. (A.R. 469); Flow Diagrams depicting the development of multiple myeloma. (A.R. 572-575). References to the Appendix Record – the contents of which were agreed to by the parties – are set forth as "A.R.____."

"petitioner"), was substituted as the proper party plaintiff, and filed an Amended Complaint alleging that her deceased husband's disease and death were the result of his exposure to diesel exhaust while employed by CSX, and that she was entitled to recover damages under the FELA.

At the conclusion of expert discovery, CSX filed a motion to exclude all medical causation evidence in this matter alleging that petitioner was unable to establish that exposure to diesel exhaust had been proven by "good science" to cause multiple myeloma (*i.e.* general causation), and unless petitioner could prove general causation, she was prevented from establishing that her decedent's exposure to diesel exhaust caused his multiple myeloma. In the alternative, CSX requested an evidentiary hearing to flesh out whether petitioner's expert witnesses' opinions were sufficiently reliable to be admissible under *Daubert v. Merrell Dow Pharmaceticals, Inc.*, 509 U.S. 579 (1993) and *Wilt v. Buracker*, 191 W.Va. 39, 443 S.E.2d 196 (1993).

The trial court granted respondent's request for an evidentiary hearing, and framed the issue for consideration during the hearing as "[t]he general causation hypothesis at issue in this case is as whether or not excessive exposure to diesel exhaust causes multiple myeloma." (A.R. 754)(emphasis added). A two-day evidentiary hearing was held in October 2011 during which petitioner's three expert witnesses, Peter Infante, Dr.P.H.[2], Lawrence Goldstein, Ph.D.[3], and

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[2]Dr. Infante's qualification as an expert in epidemiology is described in ¶¶ 4-15 of petitioner's proposed Findings of Fact and Conclusions of Law Regarding Peter Infante. (A.R. 669-672). *See also* Infante *Curriculum Vitae* (A.R. 269-296); Infante September 9, 2010 Report. (A.R. 315-317).

[3]Dr. Goldstein's qualification as an expert in toxicology is described in ¶¶ 4-10 of petitioner's proposed Findings of Fact and Conclusions of Law Regarding Lawrence Goldstein. (A.R. 650-652). *See also* Goldstein *Curriculum Vitae*. (A.R. 241-249).

Brian G.M. Durie, M.D.[4], and respondent's two expert witnesses testified.

I. Dr. Peter Infante's Methodology.

In establishing the general causation proposition that diesel exhaust causes multiple myeloma, Dr. Infante employed the following methodology[5]: he looked at epidemiologic literature including railroad worker studies and diesel exhaust exposure and multiple myeloma; he looked at biological plausibility; he reviewed animal studies relating to diesel exhaust and benzene exposures; he looked at diesel exhaust effects on DNA and also on human lymphocytes; he took into account that diesel exhaust contains components that are carcinogenic in humans, namely benzene, pristane, and PAHs; and he looked at the components of diesel exhaust that demonstrate an elevated risk of multiple myeloma. (A.R 105-108). *See also*, Infante September 9, 2010 Report. (A.R. 315-333). Given the foregoing factors, he came to his final interpretation that there is a significant association between diesel exhaust and risk of multiple myeloma (A.R 105), and that Mr. Harris' occupational exposures to diesel exhaust were significant contributing factors and the most likely cause of his development of multiple myeloma. Infante September 9, 2010 Report. (A.R. 329).

Dr. Infante also reviewed the report of CSX's expert in epidemiology, Dr. Peter Shields, regarding his opinion of diesel exhaust as a cause of multiple myeloma. Dr. Infante noted that in many of the studies Dr. Shields cites, multiple myeloma was not evaluated separately from other

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[4]Dr. Durie's qualification as an expert in hematology, oncology and multiple myeloma is described in ¶¶ 4-7 of petitioner's proposed Findings of Fact and Conclusions of Law Regarding Brian G.M. Durie. (A.R. 692-693). *See also* Durie *Curriculum Vitae*. (A.R. 501-571).

[5]Dr. Infante used the same methodology that was employed by the International Agency for Research on Cancer (IARC). (A.R. 101)

lymphomas making it difficult to determine the relative risk of multiple myeloma. Dr. Shields also did not consider the impact of the healthy worker effect on the risk of multiple myeloma in the studies he reviewed in making his determination about diesel exhaust exposure and relative risk of multiple myeloma. (A.R. 108-111). *See also* Infante September 9, 2010 Report (A.R. 328).

II. Dr. Lawrence Goldstein's Methodology.

Dr. Goldstein used the "weight of the evidence" risk assessment framework used by government and public interest agencies and industry[6] in establishing the biological plausibility aspect of the causation relationship between diesel exhaust and multiple myeloma as well as the general causation proposition that diesel exhaust causes multiple myeloma. (A.R. 43). His analysis in this case was the same "weight of the evidence" analysis that he used when he was employed by the Electric Power Research Institute and the World Health Organization. (A.R. 46). He began his analysis with the question, "what is the evidence that diesel exhaust causes cancer in general?" (A.R. 22). He reviewed the scientific studies and took advantage of aspects of the research that had already been compiled from various sources in the peer-reviewed literature, specifically reports from governmental agencies and international agencies. (A.R. 22-23).

Dr. Goldstein explained that he personally reviewed the animal literature regarding PAHs

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[6]Dr. Goldstein relied on the analysis frameworks established by U.S. EPA, IARC, and by researchers at the Electric Power Research Institute. The First Circuit explained the "weight of the evidence" approach in a recent decision. "This 'weight of the evidence' approach to making causal determinations involves a mode of logical reasoning often described as 'inference to the best explanation,' in which the conclusion is not guaranteed by the premises." *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11, 17 (1st Cir. 2011) *cert. denied* 564 U.S. ___ 132 S. Ct. 1002, 181 L. Ed. 2d 734 (2012) *citing Bitler v. A.O. Smith Corp.*, 391 F.3d 1114, 1124 n.5 (10th Cir. 2004).

(polycyclic aromatic hydrocarbons, a constituent of diesel exhaust), coal tar, diesel exhaust, and their impacts on the animal model (A.R. 24); he considered the various avenues of exposure and the systemic nature of PAHs (A.R. 25-33); he considered the fact that diesel exhaust and its components can cause DNA damage (A.R. 24-39, 42-43); he considered that diesel exhaust is a probable human carcinogen (A.R. 21, 23, 25); and he relied on his own research concerning PAHs to reach his judgment that it is biologically plausible that diesel exhaust causes multiple myeloma. (A.R. 21-22, 40, 51). Dr. Goldstein also indicated that it can be reasonably concluded that Mr. Harris' exposure to diesel exhaust was a major factor in his development of multiple myeloma. "The weight of the scientific and medical evidence from humans, animal studies, studies with tissues and cells using diesel exhaust, closely related pryrogenic materials and chemicals known to be in diesel exhaust supports this conclusion as does an understanding of the conditions under which Mr. Harris worked for 29 years." Goldstein August 2, 2010 Report. (A.R. 264).

III. Dr. Brian G.M. Durie's Methodology.

Dr. Durie used the broad framework of the Bradford Hill viewpoints[7] in establishing the general causation proposition that diesel exhaust causes multiple myeloma. He looked at the

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[7]*See* Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc'y Med. 295 (1965). Briefly, Hill's considerations for assigning causation can be summarized as strength, consistency, specificity, temporality, biological gradient (dose response), plausibility, coherence, experiment and analogy. Scientists utilize the various considerations in determining causation. However, not all of the considerations are needed to satisfy an inference of causation. "Although Hill identified nine viewpoints, it is generally agreed that this list is not exhaustive and that no one type of evidence must be present before causality may be inferred. For example, when a group from the National Cancer Institute was asked to rank the different types of evidence, it concluded that '[t]here should be no such hierarchy.'" *Milward, supra*, 639 F.3d at 17 *citing* Michele Carbon et al., *Modern Criteria to Establish Human Cancer Etiology*, 64 Cancer Res. 5518, 5522 (2004); *See also* Sheldon Krimsky, *The Weight of Scientific Evidence in Policy and Law*, 95 Am. J. Pub. Health S129, S130 (2005).

consistency of the data, strength of the data, specificity of the data, biologic plausibility, coherence, animal data, and analogies. (A.R. 467).

Dr. Durie explained that he reviewed the epidemiological literature personally, and relied on Dr. Infante's review of that literature; he took into account animal studies that he personally reviewed as well as the review performed by Dr. Lawrence Goldstein; he considered aspects of his patients' clinical development of multiple myeloma; he considered the medical and physiological development of myeloma in the microenvironment of the bone marrow; he considered the fact that diesel exhaust and its components can cause DNA damage; he considered that diesel exhaust is a probable human carcinogen; he also considered Mr. Harris' clinical picture as demonstrated by his medical records and the deposition testimony; and he relied on his own research concerning myeloma patients to reach his judgment that diesel exhaust causes multiple myeloma. (A.R. 471-472). *See also* Durie August 11, 2010 Report. (A.R. 576-581).

IV. The Trial Court Excluded Each of Petitioner's Experts.

By Memorandum Orders entered August 16, 2012, the trial court granted respondent's motions to exclude petitioner's three expert witnesses – finding that petitioner's experts had not utilized the proper methodology in reaching their conclusions. (A.R. 774, 793, 804). While framing the Memorandum Order as an analysis of the petitioner's three experts' methodology, the trial court centered on a what it characterized as a lack of consistent epidemiologic studies on the stated hypothesis, including perceived flaws in the scientific literature suggested by respondent's experts (A.R. 765-766, 782-783, 784-789, 792, 801-802); a lack of any consensus statement from governmental or international agencies or organizations charged with reviewing

the issue that diesel exhaust causes multiple myeloma (A.R. 766, 783, 802); and most importantly the finding that the general causation hypothesis that exposure to diesel exhaust causes multiple myeloma has not been proven. (A.R. 766, 783, 802).

With no expert witnesses to support her claim, petitioner agreed with the respondent to jointly move the trial court for entry of summary judgment in favor of the respondent so that the trial court's rulings on petitioner's experts could be appealed. The trial court entered an Order Granting Summary Judgment on August 21, 2012 against petitioner. (A.R. 754-757). It is this August 21, 2012 Order from which petitioner appeals.

SUMMARY OF ARGUMENT

Ignoring the interplay between the Federal Employers' Liability Act with its reduced causation standard and the admissibility of expert witness testimony under Rule 702, the trial court required petitioner to prove that diesel exhaust causes multiple myeloma before her well-qualified expert witnesses could testify. In essence, the trial court established the admissibility bar at a level which is not supported by the case law. Nevertheless, even under the heightened standard of admissibility applied by the trial court, petitioner established the necessary reliability prong of her expert witnesses' opinions so as to comply with the holdings of *Daubert/Wilt.*

STATEMENT REGARDING ORAL ARGUMENT AND DECISION

Because the issue of the interplay between the Federal Employers' Liability Act's causation standard and the analysis necessary under *Daubert/Wilt*, *supra*, is one of first impression in West Virginia, and the trial court's exercise of discretion in applying the *Daubert/Wilt* holdings is unsustainable given settled law, oral argument is appropriate under Rev. R.A.P. 19(a), and disposition by an opinion would be beneficial to the state judiciary and bar.

STANDARD OF REVIEW

"[W]hen a circuit court excludes expert testimony as unreliable under the [Rule 702] *Daubert/Wilt* gatekeeper analysis, we will review the circuit court's method of conducting the analysis *de novo*." *In re Flood Litigation Coal River Watershed*, 222 W.Va. 574, 580, 668 S.E.2d 203, 209 (2008) *citing San Francisco v. Wendy's Int'l., Inc.,* 221 W.Va. 734, 741, 656 S.E.2d 485, 492 (2007). Likewise, "a circuit court's decision to grant a party a summary judgment under Rule 56, W.Va. R. Civ. P., is reviewed *de novo*." *San Francisco v. Wendy's Int'l., Inc.,* 221 W.Va. 734, 740, 656 S.E.2d 485, 491 (2007) *citing* Syllabus Pt. 1, *Painter v. Peavy*, 192 W.Va. 198, 451 S.E.2d 755 (1994).

ARGUMENT

At the outset, one cannot lose sight of the fact that petitioner's cause of action was brought pursuant to the Federal Employers' Liability Act with its "feather-weight" standard of causation. Indeed, petitioner's burden of proving causation was significantly relaxed compared to the burden in an ordinary negligence action. See *Consolidated Rail Corp. v. Gottshall*, 512 U.S. 532, 543, 114 S. Ct. 2396, 2404, 129 L. Ed. 2d 427 (1994). The causation standard applicable to Mr. Harris' claim was simply "if [CSX's] negligence played a part – no matter how small – in bringing about [Mr. Harris'] injury." *CSX Transp., Inc. v. McBride*, 564 U.S. ___, 131 S.Ct. 2630, 2644 (2012).

I. The Liberal Standard of Causation Applicable Under the Federal Employers' Liability Act, 45 U.S.C. § 51, *et seq.*, Affects a Trial Court's *Daubert/Wilt* Analysis Under Rule 702, W.Va. R. Evid.

As this Court has indicated, many courts have followed the United States Supreme Court's decision of *Rogers v. Missouri Pacific Railroad Co.*, 352 U.S. 500, 506-07, 77 S. Ct.

443, 448-49, 1 L. Ed. 2d 493 (1957), in which the Court established the following test for a jury case:

> Under [the 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. It does not matter that, from the evidence, the jury may also with reason, on grounds of probability, attribute the result to other causes, including the employee's contributory negligence. Judicial appraisal of the proofs to determine whether a jury question is presented is narrowly limited to the single inquiry whether, with reason, the conclusion may be drawn that negligence of the employer played any part at all in the injury or death. (footnotes omitted and emphasis added).

McGraw v. Norfolk & W. Ry., 201 W. Va. 675, 681-682, 500 S.E.2d 300, 306-07 (1997); see also *Gardner v. CSX Transp.*, 201 W. Va. 490, 499, 498 S.E.2d 473, 482 (1997); *Crookham v. New York Cent. R.R. Co.*, 144 W. Va. 196, 203-204, 107 S.E.2d 516, 520 (1959) ("Though negligence of an employer constitutes only the 'slightest' part in producing the injury, and though the proof establish that the injury may probably have resulted from causes other than negligence of the employer, the question remains one for jury determination if the 'proofs justify with reason the conclusion that employer negligence played any part, even the slightest, in producing the injury.'")

Additionally, in a FELA case, "[w]here the facts are in dispute, and the evidence in relation to them is that from which fair-minded men may draw different inferences," the case should go to the jury. *Tiller v. Atlantic C. L. R. Co.*, 318 U.S. 54, 67-68 (1943). Discretion to engage in common sense inferences regarding issues of causation and fault is exclusively vested with the jury "in all but the infrequent cases where fair-minded jurors cannot honestly differ whether fault of the employer played any part in the employee's injury." *Walden v. Illinois Cent.*

Gulf R.R., 975 F.2d 361, 364 (7th Cir. 1992), *citing Rogers,* 352 U.S. at 510, 77 S. Ct. 443.

The United States Supreme Court noted that in FELA cases, the role of the court is not to search the record for conflicting circumstantial evidence and to take the case from the jury because the evidence equally supports inconsistent and uncertain inferences. Instead, it is the function of the jury, not the court, to select among conflicting inferences and conclusions. *See Gallick v. Baltimore and Ohio R. Co.*, 372 U.S. 108, 113 (1963). *See also Lavender v. Kurn*, 327 U.S. 645, 653 (1946) ("Whenever facts are in dispute or the evidence is such that fair-minded men may draw different inferences, a measure of speculation and conjecture is required on the part of those whose duty it is to settle the dispute by choosing what seems to them to be the most reasonable inference. Only when there is a complete absence of probative facts to support the conclusion does a reversible error appear.")

Where the admissibility of expert testimony is challenged, the issue becomes the interaction between the more liberal causation standard applicable under the FELA, and the analysis required by the *Daubert/Wilt* holdings. As one district court indicated, "it is not difficult to see the tension between the *Daubert* standard for admission of expert testimony and the FELA standard on causation for submission of a case to a jury." *Savage v. Union Pacific Railroad Company,* 67 F. Supp. 2d 1021, 1027 (E.D. Ark. 1999).

The Second Circuit has also recognized this tension in *Wills v. Amerada Hess Corp.*, a Jones Act case[8].

> Although we agree with the Sixth and Ninth Circuits that *Daubert* applies in the context of the Jones Act, we recognize that *Daubert's*

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[8]The Jones Act employs the same standard of causation as the FELA by incorporating the FELA into the Jones Act. *See* 46 U.S.C. app. §§ 688, *et seq.*

> relevancy inquiry may be affected by the reduced statutory burden of proof in such cases. See *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1321 (9th Cir. 1995) (noting, in the context of remand from the Supreme Court, that, where the burden of proof to establish causation was "by a preponderance of the evidence," expert testimony that would fail to satisfy *Daubert's* reliability inquiry might nonetheless satisfy the relevance inquiry because of the reduced burden of proof). We express no opinion on this issue of whether and how *Daubert's* relevancy inquiry is affected by a reduced burden of proof, however, as our conclusion that Dr. Bidanset's testimony was properly excluded rests solely on the fact that the testimony failed to satisfy any of the *Daubert* factors for assessing reliability.

379 F.3d 32, 47 n 8 (2nd Cir. 2004).

Moreover, the Third Circuit opinion of *Hines v. Consolidated Rail Corp.*, 926 F.2d 262 (3d. Cir. 1991) supports the proposition that a lower substantive standard of causation can affect the admissibility of expert testimony:

> [T]he [causation] standard under FELA can significantly influence a determination of the admissibility of [expert] testimony. By enacting FELA, Congress desired to "secure jury determinations in a larger proportion of cases than would be true of ordinary common law actions." Indeed, jury determinations were intended to be part of the FELA remedy.

Hines, 926 F.2d at 269, *quoting Boeing Co. v. Shipman*, 411 F.2d 366, 371 (5th Cir. 1969) (internal citations omitted). The Third Circuit noted that the FELA required a greater role from juries in determining the importance of expert testimony as compared to the role of juries in common law negligence cases. "[I]t is the task of the jury and not the medical witnesses to make a legal determination regarding causation." *Hines*, 926 F.2d at 269 *citing Sentilles v. Inter-Caribbean Shipping Corp.*, 361 U.S. 107, 109 (1959).

Even after the Supreme Court decided *Daubert*, the Third Circuit again indicated, in

discussing the causation standard in FELA cases, that in "analyzing reliability for the purposes of litigation not for the purposes of science, the substantive standard of causation can affect the standard of admissibility." *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 761 n. 31 (3d Cir. 1994).

A dichotomy exists in the FELA setting between how state courts and federal courts have applied the interpretation of evidence rule 702. Some state courts, applying their own evidence rules as well as their interpretation of the applicable state rule 702, have been more been more lenient in permitting expert testimony in FELA cases given the lower causation standard.

The Michigan appellate court recently was called upon to apply that state's Rule 702 analysis to an FELA case in *Avery v. Grand Trunk Western Railroad*. *Avery* involved a claim that the railroad worker's brain tumor was the result of his exposure to toxic chemicals. The court noted that the state's evidence rule on expert witnesses controlled the admissibility of expert witness opinions, not the federal counterpart. Reversing the exclusion of the expert and the trial court's grant of summary judgment, the court agreed that the expert had not established a "direct causal link" between Avery's occupational exposures and his brain cancer, but he was not required to do so under the FELA.

> [A] FELA action does not require such a link and is markedly relaxed. In order to reach the trier of fact in a FELA action, a plaintiff need only offer proof justifying a conclusion the defendant's "negligence played any part, even the slightest, in producing the injury or death for which damages are sought. *Rogers, 352 U.S. at 506.*

2011 Mich. App. LEXIS 1113 *10 (2011), *app. denied*, 2012 Mich. LEXIS 593 (2012) (unpublished). The court concluded "that the trial court erred when it excluded Dr. Abramson's

testimony on the ground that it was not relevant to the issue of causation in this case because Dr. Abramson's testimony established some reason for concluding that there is a link between Avery's occupational exposures and brain cancer." 2011 Mich. App. LEXIS 1113 *11 (2011).

A California appellate court applied similar logic under the Jones Act in *Shelby v. Seariver Maritime, Inc.*, 2011 Cal. App. Unpub. LEXIS 1230 (Cal. Ct. App. 2011) (not published in Cal Rptr.2d)[9]. In rejecting a challenge to the sufficiency of expert testimony regarding causation of illness, the *Shelby* court observed that the basis for an expert's opinion "was not speculation or conjecture, but rather his review of over 35 peer-reviewed articles, his interview and examination of plaintiff, his review of plaintiff's medical and occupational records, and his specialized knowledge of benzene and how the human body reacts to it." 2011 Cal. App. Unpub. LEXIS 1230 at 40. The court expressly recognized that most of the studies on which the expert relied "found the evidence of a causal relationship between benzene and renal cell carcinoma inconclusive, nonexistent, or not statistically significant," and that the expert acknowledged certain flaws in the studies. *Id.* at 21-27. In spite of these limitations, the *Shelby* court found that the expert's opinions supported the jury's finding that the defendant's "negligence in facilitating or failing to prevent plaintiff's exposure to harmful levels of benzene and other hydrocarbons during his 17 years of handling petroleum products and other chemicals on SeaRiver vessels played some part, *however small*, in his kidney cancer and related harm." *Id.* at 40-41 (emphasis

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[9]The *Shelby* case is an unpublished California opinion subject to Cal. Rules of Court 8.1115(a), which provides that an opinion "not certified for publication or ordered published must not be cited or relied on by a court or a party in any other action." However, courts interpreting Rule 8.1115 have found the rule to permit reference to unpublished decisions for some limited purposes. *See*, *Sheikh v. Holder*, 379 Fed. Appx. 697, 700 fn. 2 (9th Cir. 2010) (not published in F.3d) (citation of unpublished case appropriate to illustrate statutory requirements). Here, the petitioner refers to *Shelby* for comparison to its facts, not as binding authority on this Court.

added).

Federal courts, on the other hand, have determined that *Daubert* still applies when considering whether an expert's opinion is sufficiently reliable under Rule 702, Fed. R. Evid. However, most of these decisions recognize that the expert opinions must merely demonstrate that the exposure played some role in causing plaintiff's injuries.

In *Taylor v. Union Pac. R.R. Co.*, the court held that "[i]n the specific instance of a claim of alleged toxic exposure under the FELA, 'as long as plaintiff's expert presents scientifically reliable evidence that the toxic exposure could have played some role, however small, in causing plaintiff's injuries, the testimony should be admitted[.]'" Nonetheless, the federal 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 . . . to provide any evidence of causation, it must be excluded[.]" (citation and quotation marks omitted). *Taylor*, 2010 U.S. Dist. LEXIS 96802 * 11 (S.D. Ill. Sept. 16, 2010).

In *Savage v. Union Pacific Railroad Co.* the district court recognizing that the standard for causation under FELA and the *Daubert* standard for admission of expert testimony are somewhat at odds with each other, and concluded:

> To recapitulate, then, as long as plaintiff's expert presents scientifically reliable evidence that the toxic exposure could have played some role, however small, in causing plaintiff's injuries, the testimony should be admitted . . . . On the other hand, *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 inferential link that undergrids it-fails under *Daubert* to provide any evidence of causation, it must be excluded . . . . (Internal

quotations and citations omitted).

67 F. Supp. 2d at 1028.

This Court in *Jenkins v. CSX Transportation, Inc.*, 220 W.Va. 721, 649 S.E.2d 294 (2007) discussed the issues surrounding expert witnesses in a FELA case as it relates to whether an individual is qualified as an expert. While the main import of the *Jenkins* decision involved discovery sanctions, a portion of the decision did discuss plaintiff's attempt to use a neuropsychologist to establish medical causation. Without going into a detailed *Wilt* analysis, the Court found that the neuropsychologist was not qualified to give such an opinion. The Court then indicated "[W]e were, of course, mindful of the fact 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." *Rogers v. Missouri Pacific Railroad Co.,* 352 U.S. 500, 506, 77 S. Ct. 443, 448, 1 L. Ed. 2d 493, 499 (1957), and then went on to explain:

> This does not mean, however, 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. *See Oglesby v. Southern Pacific Transp. Co.,* 6 F.3d 603, 608 (9th Cir.1993). FELA plaintiffs still must demonstrate some causal connection between a defendant's negligence and their injuries. *Id*[.]

220 W.Va. at 731-732, 649 S.E.2d at 304-305, *citing Claar v. Burlington Northern R.R. Co.*, 29 F.3d 499, 503 (9th Cir. 1994). Further explaining the FELA standard of causation, the Court noted that "*the negligence of the defendant must have contributed to the cause of the injury in some degree.*" 220 W.Va. at 732, 649 S.E.2d at 305, *citing* Syllabus Point 2 of *Crookham v.*

New York Cent. R.R. Co., 144 W.Va. 196, 107 S.E.2d 516 (1950) (emphasis in original).

In present case, petitioner has presented reliable expert evidence that the claimed illness (multiple myeloma) was caused at least in part by her decedent's chronic exposure to the toxic diesel exhaust. The ultimate decision on the issue of causation should have been left to the jury. Notwithstanding the FELA "feather-weight" standard of causation and the established rule that FELA claims should not be dismissed on summary judgment unless there is absolutely no reasonable basis for a jury to find for the plaintiff, the trial incorrectly granted respondent's motion to exclude petitioner's expert witness which ultimately lead to the dismissal of the case on summary judgment grounds.

II. West Virginia Law Does Not Require a Toxic Tort Plaintiff to Prove General Causation (That Diesel Exhaust Causes Multiple Myeloma) Before Her Expert Witnesses Are Permitted to Testify in a Toxic Tort Case.

The trial court held that plaintiff must prove "general causation" before she is entitled to recover under any theory of liability. "The general causation hypothesis at issue in this case is whether or not excessive exposure to diesel exhaust causes multiple myeloma." (A.R. 754). Absent from the trial court's ruling is any citation to a West Virginia case which requires petitioner to establish "general causation" before her experts can reach the conclusion that Mr. Harris's exposure to diesel exhaust caused his multiple myeloma and ultimate death.

General causation is an epidemiologic, rather than a legal, concept. "Epidemiology focuses on the question of general causation (i.e., is the agent capable of causing disease?) rather than that of specific causation (i.e., did it cause disease in a particular individual?)." Federal Judicial Center, *Reference Manual on Scientific Evidence* 336 (2d ed. 2000). General causation, as an epidemiologic term, implies a host of epidemiologic concepts, including temporal

relationships, strength of the causal association, dose-response relationships, replication of findings, biological plausibility, alternative explanations, the effect of cessation of exposure, and consistency with other scientific knowledge. *Reference Manual*, *supra,* at 375.

In discussing the burden of proof necessary to connect a defendant's tortious conduct as a factual cause of a plaintiff's harm, the comments to the Third Restatement of Torts explains 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. So long as the plaintiff introduces admissible and sufficient evidence of factual causation the burden of production is satisfied.[10]" Restatement (3d) Torts: Liability for Physical Harm, § 28, cmt. c(1) (2010).

As this Court has previously held, to prevail on a FELA claim, a plaintiff is required to "'prove the traditional common law elements of negligence: duty, breach, foreseeability, and causation.'" *Gardner v. CSX Transp.*, 201 W. Va. 490, 499, 498 S.E.2d 473, 482 (W. Va. 1997). Likewise, in *Jenkins*, *supra*, the court explained what was needed to demonstrate that the defendant railroad's negligence "contributed proximately, in whole or in part, to plaintiff's injury."

> Medical testimony to be . . . sufficient to warrant a finding by the jury of the proximate cause of an injury is not required to be based upon a reasonable certainty that the injury resulted from the negligence of the defendant. All that is required to render such testimony . . . sufficient to carry it to the jury is that it should be of such character as would *warrant a reasonable inference by the jury*

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[10]Petitioner's expert witnesses concluded that her decedent's exposure to diesel exhaust was causative in his development of multiple myeloma, implicit in which is the general causation opinion that diesel exhaust causes multiple myeloma. *See Gates v. Texaco, Inc.*, 2008 Del. Super. LEXIS 441 (Del. Super. Ct. Mar. 20, 2008) ("'[T]he Court agrees with Plaintiff that 'implicit in Dr. Goldstein's opinion that Mr. Gates's [leukemia was] caused by his benzene exposure at the refinery is [his] opinion that benzene can cause CMML...'") *aff'd* 962 A.2d 257 (2008).

> that the injury in question was caused by the negligent act or conduct of the defendant." Syllabus point 1, in part, *Pygman v. Helton,* 148 W.Va. 281, 134 S.E.2d 717 (1964).

Jenkins, 220 W. Va. at 729, 649 S.E.2d at 302 (2007) (Emphasis added).

This Court has never recognized general causation as an element of a plaintiff's proof in any tort case, much less a toxic tort case[11]. In order to recover for the negligence of another, a plaintiff must show that the negligence proximately caused his or her injuries. *Crane & Equip. Rental Co. v. Park Corp.*, 177 W. Va. 65, 69, 350 S.E.2d 692, 696 (1986), *citing* Syl. Pt. 3, *Pygman v. Helton*, 148 W. Va. 281, 134 S.E.2d 717 (1964). *See also*, *Perry v. Melton*, 171 W. Va. 397, 400, 299 S.E.2d 8, 11 (1982) (to establish liability, negligence must be both the cause-in-fact of the injury, as well as the proximate cause). Proximate cause is a jury question so long as "the evidence relating to it is conflicting, or when the facts, though undisputed, are such that reasonable men may draw different conclusions from them." *Sexton v. Grieco*, 216 W. Va. 714, 716, 613 S.E.2d 81, 83 (2005), *quoting* Syl. Pt. 4, *Pygman*, 148 W. Va. 281, 134 S.E.2d 717 (1964).

West Virginia's and Illinois' case law on causation are similar, and while not controlling an analysis of the Illinois law is helpful in deciding the issue especially given the paucity of West Virginia authority. In *Donaldson v. Central Illinois Public Service Co.,* the Illinois Supreme Court had before it a toxic tort case in which plaintiffs alleged that environmental exposure to coal tar from a nearby coal gasification plant caused their children to develop neuroblastoma, a

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[11]Indeed, only two West Virginia Supreme Court cases even mention the term "general causation." *See Jenkins*, *supra*, (plaintiff offered an expert to testify on the issue of general causation and solvent injuries to the brain) and *San Franciso v. Wendy's International, Inc.,* 221 W.Va. 734, 758, 656 S.E.2d 485, 509 n 12 (2007) (Benjamin, J. *dissenting*) (discussing differential diagnosis, general causation, and appropriateness of the former's ability to establish causation using the latter).

cancer of the peripheral nervous system. Neuroblastoma is so rare that epidemiologic studies have not been conducted to determine its cause. After denying defendants' motions for summary judgment based on general causation and refusing to exclude plaintiffs' experts, a jury verdict was rendered for plaintiffs. The defendants appealed, arguing much like CSX in the case *sub judice*, that the judgment had to be reversed because of lack of proof of general causation, *i.e.*, that exposure to coal tar can even cause neuroblastoma.

Illinois' Supreme Court held

> Illinois law does not define causation in terms of "generic" or "specific" causation. Rather, our case law clearly states that in negligence actions, the plaintiff must present evidence of proximate causation, which includes both "cause in fact" and "legal cause." *Thacker*, 151 Ill. 2d at 354; *Smith v. Eli Lilly & Co.*, 137 Ill. 2d 222, 232, 148 Ill. Dec. 22, 560 N.E.2d 324 (1990). A plaintiff may show "cause in fact" under the substantial factor test, showing that the defendant's conduct was a material element and substantial factor in bringing about the alleged injury. *Thacker*, 151 Ill. 2d at 354-55; *Lee v. Chicago Transit Authority*, 152 Ill. 2d 432, 455, 178 Ill. Dec. 699, 605 N.E.2d 493 (1992).

Donaldson v. Central Illinois Public Service Co., 199 Ill. 2d 63, 90-91, 767 N.E. 2d 314, 331-332 (2002) *overruled on other grounds by People v. Simons*, 821 N.E.2d 1184 (Ill. 2004).

Thus, petitioner would suggest that under West Virginia law she had no requirement to establish general causation (excessive exposure to diesel exhaust causes multiple myeloma) as required by the trial court before she was permitted to establish that her decedent's multiple myeloma resulted from his work place exposure to diesel exhaust[12]. This Court should reject the notion that a toxic tort plaintiff must prove general causation as a separate element of a plaintiff's

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[12]Interestingly, while the plaintiff' experts in *Jenkins v. CSX*, *supra*, could not make a medical diagnosis of a solvent-related neurological disease, petitioner's experts related her deceased husband's multiple myeloma to his exposure to diesel exhaust during his employment with CSX.

required proof of causation, and instead should reaffirm its prior holding that "[a]ll that is required to render such [causation] testimony . . . sufficient to carry it to the jury is that it should be of such character as would *warrant a reasonable inference by the jury* that the [disease] in question was caused by the negligent act or conduct of the defendant." *See* Syl. Pt. 4, *Pygman, supra*, 148 W. Va. 281, 134 S.E.2d 717.

III. Even Assuming That the FELA Standard of Causation Has No Impact on a *Daubert/Wilt* Analysis, and That Petitioner Was Required to Establish General Causation, Petitioner's Expert Witnesses' Methodology Met the Legal Requirements to Render Their Testimony Admissible, and a Jury Should Have Been Permitted to Decide the Ultimate Issue of Causation.

Removing the causation issue from the jury's consideration in the first instance, the trial court adopted the respondent's suggestion that petitioner failed to establish the requirement that petitioner must establish that exposure to diesel exhaust had been proven by "good science" to cause multiple myeloma, and that her experts' opinions were inadmissible as a result. (A.R. 767, 766, 783, 802). Therefore, the trial court's exclusion of plaintiff's expert witnesses' testimony, while couched in terms of a *Daubert/Wilt* analysis, is really nothing more than its conclusion that the medical and scientific evidence does not prove that diesel exhaust is causative of multiple myeloma[13].

It is well-settled law that "plaintiffs [do not] have to prove their case twice – they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3rd Cir. 1994) *citing*

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[13]It is worth noting that this Court upheld an award of workers' compensation benefits to a claimant who developed multiple myeloma after exposure to diesel exhaust. *See West Virginia Division of Highways v. Cutlip*, No. 050404, April 17, 2006.

Bourjaily v. United States, 483 U.S. 171, 175, 107 S. Ct. 2775, 2778, 97 L. Ed. 2d 144 (1987). *See also U.S. v. Mitchell*, 365 F.3d 215, 235-236 (3rd Cir. 2004); *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1233 (10th Cir. 2004); *Toomey v. Nextel Communications, Inc.*, 2004 U.S. Dist. LEXIS 30793 *8 (N.D. Cal. 2004).

Trial courts are not empowered:

> [T]o determine which of several competing scientific theories has the best provenance. *Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct. The proponent of the evidence must show only that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.

Milward v. Acuity Specialty Products Group, Inc., 639 F.3d 11, 15 (1st Cir. 2011) *cert. denied* 564 U.S. ___ 132 S. Ct. 1002, 181 L. Ed. 2d 734 (2012) (internal quotations and citations omitted). *See also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F.Supp. 2d 584, 595 (D.N.J. 2002) ("[A] trial court should admit expert testimony 'if there are "good grounds" for the expert's conclusion' notwithstanding the judge's belief that there are better grounds, for some alternative conclusion.")

"When scientific evidence is proffered, a circuit court in its 'gatekeeper' role under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), and *Wilt v. Buracker*, 191 W.Va. 39, 443 S.E.2d 196 (1993), *cert. denied*, [511] U.S. [1129], 114 S.Ct. 2137, 128 L.Ed.2d 867 (1994), must engage in a two-part analysis in regard to the expert testimony. First, the circuit court must determine whether the expert testimony reflects scientific knowledge, whether the findings are derived by scientific method, and whether the work product amounts to good science. Second, the circuit court must ensure that the

scientific testimony is relevant to the task at hand." *San Francisco v. Wendy's Int'l, Inc.*, 221 W.Va. 734, 751, 656 S.E.2d 485, 502 (2007) (Davis, C.J. *concurring*) *citing* Syl. pt. 4, *Gentry* [*v. Mangum*], 195 W.Va. 512, 466 S.E.2d 171 (1995)[14]. "Further assessment should then be made in regard to the expert testimony's reliability by considering its underlying scientific methodology and reasoning." Syl. Pt. 2, *Wilt v. Buracker*, 1919 W.Va. 39, 442 S.E.2d 196 (1993).

"The very purpose of *Daubert*[*/Wilt*], '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.*'" *Wendy's Int'l, Inc.,* 221, W.Va. at 753, 656 S.E.2d at 504 (Benjamin, J. *dissenting*) *citing Kumho* [*Tire Co. v. Carmichael*], 526 U.S. [137], 152 [(1999)] (emphasis in original). *See also Milward*, 639 F.3d at 15. "Evaluating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses[.] Instead, under *Daubert/Wilt* and *Gentry* a trial court:

> conducts an inquiry into the validity of the underlying science, looking at the soundness of the principles or theories and the reliability of the process or method as applied to the case. *The problem is not to decide whether the proffered evidence is right, but whether the science is valid enough to be reliable."*

Wendy's Int'l, 221 W.Va. at 743, 656 S.E.2d at 494 (emphasis in original) *citing Gentry,* 195 W.Va. at 519, 466 S.E.2d at 178, *quoting in part, In re Paoli R.R. Yard PCB Litigation,* 35 F.3d at 749.

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[14]Petitioner advised the trial court during the first day of the evidentiary hearing that the testimony proffered was scientific in nature. (A.R. 5). Additionally, respondent CSX did not dispute the qualifications of petitioner's expert witnesses or that the evidence was relevant to a fact in issue.

However, "trial courts should be mindful that scientific evidence presented through expert witnesses is presumptively admissible." *Wendy's Int'l, Inc.*, 221, W.Va. at 751, 656 S.E.2d 502 (Davis, C.J. *concurring*). Because of the "liberal thrust" of the rules pertaining to experts, the circuit court should have erred on the side of admissibility as it relates to petitioner's expert witnesses' opinions since "[d]isputes as to the strength of an expert's credentials, mere differences in the methodology, or lack of textual authority for the opinion go to weight and not to the admissibility of their testimony." *Gentry v. Mangum*, 195 W.Va. 512, 525-27, 466 S.E.2d 171, 184-86 (1995) *citing* II Franklin D. Cleckley, *Handbook on Evidence for West Virginia Lawyers* § 7-2(A) at 24 ("[t]his standard is very generous and follows the general framework of the federal rules which favors the admissibility of all relevant evidence"). As this Court recently noted, "most of the cases in which expert testimony is offered involve only qualified experts disagreeing about the interpretation of data that was obtained through standard methodologies[,] *Daubert/Wilt* is unlikely to impact upon those cases." *Walker v. Sharma*, 221 W.Va. 559, 564, 655 S.E.2d 775, 780 (2007) *citing Gentry v. Mangum,* 195 W.Va. 512, 522, 466 S.E.2d 171, 181 (1995) *accord* Fed.R.Evid. 702 advisory committee's note (2000 amends.) (noting that "review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule").

A. The Petitioner's Expert Witnesses' Methodology Was Reliable.

As discussed above, to be admissible an expert witness' opinions must merely reflect scientific knowledge derived by a reliable scientific method[15]. Here, on the other hand, the trial

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[15]Additionally, the extensive experience and specialize expertise of petitioner's expert witnesses augment the reliability of their reasoning and methodology. *See Joiner v. General Electric Company*, 78 F.3d 524 , 532 (11th Cir. 1996) (indicating that expertise "has some bearing on the determination of the

court went beyond its "gatekeeper" role and usurped the finder of facts' responsibility to determine causality. Indeed, the trial court's "subject hypothesis" undermines its entire analysis since the court is not permitted to chose between which sets of experts are correct.

As discussed above, while the trial court is to be a gatekeeper as to the admissibility of expert witness opinions – those opinions must merely reflect scientific knowledge derived by a reliable scientific method to be admissible[16]. Here, the trial court should have acted as the evidentiary gatekeeper, not a goalkeeper. *See King v. Burlington Northern Santa Fe Railway Company*, 277 Neb. 203, 227, 762 N.W. 2d 24, 35 (2009).

The trial court referenced in its Memorandum Orders numerous issues that it felt undermined the plaintiff's expert witnesses' opinions that diesel exhaust and its constituents caused the petitioner's decedent's multiple myeloma. For the sake of simplicity, petitioner will discuss each area below.

1. Trial Court's Findings Regarding Epidemiologic Studies.

The trial court's findings regarding epidemiologic studies and their import in the causal determination in the case at bar overemphasized the studies' contribution to the admissibility of petitioner's expert witnesses opinions, and are generally contrary to the case law.

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reliability of the underlying reason or methodology"); *Hopkins v. Dow Corning Corning*, 33 F.3d 1116, 1125 (9th Cir. 1994) (considering the "expertise" to conclude that methodology underlying expert opinions satisfied *Daubert*); *U.S. v. Downing*, 753 F.2d 1224, 1239 (3rd Cir. 1985) (recognizing that "[t]he qualifications and professional stature of expert witnesses. . . may also constitute circumstantial evidence of the reliability of the technique.).

[16]Based on its findings of fact, the trial court appreciated that the issue for consideration was simply the methodology of the expert witnesses. "There is a subjective component to a causation analysis but only after an accepted methodology has been employed." (A.R. 761, 778, 797). However, the trial court ignored the explanation by each of petitioner's expert witness as to their methodology. See supra p. 3-6.

Initially, "[e]pidemiology is the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations." Federal Judicial Center, Reference Manual on Scientific Evidence 551 (3rd ed. 2011). Epidemiological studies establish an association between an exposure and a disease. They cannot prove causation. (A.R. 784). However, epidemiologic studies can provide a foundation for an expert to "infer and opine that a certain agent can cause a disease." *King*, 277 Neb. at 215, 762 N.W. 2d at 36.

In general, epidemiology compares the rate of disease found in a group of exposed individuals to that of an unexposed group of individuals, and then using statistical analysis determines if the comparison rate[17] found is statistically significant or more likely attributable to chance. *See*, Federal Judicial Center, Reference Manual on Scientific Evidence 573 (3rd ed. 2011). When the risk ratio is greater than 1.0, and the statistical analysis demonstrates a p-value of 0.05 or a confidence interval with a lower bound greater than 1.0, the finding is deemed to show a statistically significant excess risk of disease. *See Cook v. Rockwell International Corporation,* 580 F. Supp. 2d 1071, 1100-1106 (D. Colo. 2006) *rev'd on other grounds at* 618 F.3d 1127 (10th Cir. 2010). In essence, when a comparison ratio is above 1.0 and found to be statistically significant there is evidence of an association between the subject disease and the exposure of interest. *See generally* Federal Judicial Center, Reference Manual on Scientific Evidence 539-642 (3rd ed. 2011). However, even increases in the comparison ratio that are not statistically significant can demonstrate an excess risk, and can be used to support a causation analysis. *See* Phillip Cole testimony (A.R. 635); Peter Infante testimony. (A.R. 91-94). *See also*

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[17]The comparison is usually expressed as either an "odds ratio," "risk ratio," or "standard mortality ratio," depending on the type of study performed.

King, 277 Neb. at 233, 762 N.W. 2d at 45 ("Experts have pointed out that the lack of statistical significance does not demonstrate that there is no relationship. . . We also decline to impose a statistical significance requirement if an expert shows that others in the field would nonetheless rely on the study to support a causation opinion and that the probability of chance causing the study's results is low.") (citations omitted).

The Florida appellate court in *Berry v. CSX Transp.*, declined to require that only statistically significant studies can be used to support causation.

> Finally, we decline to adopt the railroad's suggestion that we reject "statistically insignificant" studies. The use of "statistical significance" to reject an epidemiological study has been roundly criticized by the experts in the field. See, e.g., [Michael D.] Green, [Expert Witnesses and Sufficiency of Evidence in Toxic Substance Litigation: The Legacy of Agent Orange and Bendectin Litigation, 86 Nw. U. L. Rev. 643], at 681-93[(1992).] Professor Green, for example, concludes that rejecting studies that are not statistically significant would be cursory and foolish. We find his explanation instructive:
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>> The Brock [*Brock v. Merrell Dow Pharm., Inc., 874 F.2d 307 (5th Cir. 1989)*, cert. denied, *494 U.S. 1046, 110 S. Ct. 1511, 108 L. Ed. 2d 646 (1990)]* decision, in ascribing wondrous powers to the concept of statistical significance, contributes to doubts that these matters are ones that reasonably can be mastered by generalist judges. Statistical significance addresses only random error due to the sampling inherent in any epidemiologic study. It cannot and does not speak to systematic error, which requires an informed review of the methodology employed in conducting the study. Moreover, statistical significance is merely an instrument for assisting in evaluating a study, not a truth serum that can be simplistically prescribed. 86 Nw. U. L. Rev. at 681-82.

709 So. 2d 552, 570 (Fla. Dist. Ct. App. 1st Dist. 1998). *See also Ambrosini v. Labarraque*, 101

F.3d 129 (D.C. Cir. 1996) (products liability law does not preclude recovery until a statistically significant number of people have been injured).

The rules of evidence do not "require a physician to rely on definitive published studies before concluding that exposure to a particular object or chemical was the most likely cause of a plaintiff's illness." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 154 (3d Cir. 1999). "Courts, however, should not exclude an opinion merely because there is an absence of literature on the precise issue as long as other factors demonstrate the reliability of the expert's opinion." *In re Human Tissue Prod. Liab. Litig.*, 582 F. Supp 2d 644, 656 (D.N.J. 2008), *citing Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 154 (3d Cir. 1999). "[T]he lack of scientific studies either proving or disproving the hypothesis of causality is not necessarily fatal to an expert's opinion." *In re Human Tissue Prod. Liab. Litig.*, 582 F. Supp.2d at 656-57, *citing In re Ephedra Prod. Liab. Litig.*, 393 F. Supp.2d 181, 188-89 (S.D.N.Y. 2005). *See also Bloomquist v. Wapello County*, 500 N.W.2d 1 (Iowa 1993) (recognizing proof of causation based on traditional cause-and-effect testimony in toxic tort case, even in absence of epidemiologic evidence).

Even assuming that no epidemiologic evidence exists, "[t]he absence of peer-reviewed epidemiological studies does not make it 'almost impossible' for plaintiff's experts' opinions to be admissible. Epidemiological studies are not per se required as a condition of admissibility regardless of context. Nor are such studies treated as always essential in the relevant scientific communities." *Milward*, 639 F.3d at 24 *citing Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1198 (11th Cir. 2002) ("It is well-settled that while epidemiological studies may be powerful evidence of causation, the lack thereof is not fatal to a plaintiff's case."). *See also*, Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 28 cmt. c(3) (2010) (listing federal

circuit cases holding that epidemiological data is not necessary).

Specifically, the trial court in the present matter made the following findings regarding epidemiology[18]:

- Statistical significance is a way of expressing whether or not a study's purported findings are the product of a real causal association or random chance. (A.R. 761, 778, 797).
- Most epidemiologic studies must be positive for a purported causal association to be real. (A.R. 765, 782, 801).
- If a difference between a case group and a control group is not statistically significant then there is no difference in the two studies at all. (A.R. 761, 778, 797).
- It is acceptable scientific practice to interpret as "not different" a study that shows an elevated risk that is not statistically significant. (A.R. 762, 779, 798).
- Of the 47 studies of diesel exposed workers only eight (8) purport to be positive. (A.R. 765, 782, 801).
- The epidemiologic literature investigating a causal association between railroad employment and multiple myeloma is null and not supportive of the subject hypothesis. (A.R. 765, 782, 801).
- There are approximately ten (10) published studies investigating causal link

[18]Each finding references and is based solely on the testimony of respondent's expert witness, Peter Shields, M.D., and ignored the contrary testimony of petitioner's expert witnesses.

between benzene and multiple myeloma. None of them are positive[19]. (A.R. 765, 782, 801).

- Only 5 of the 53 published studies regarding benzene exposure of non-railroad workers are positive for multiple myeloma. (A.R. 765, 782, 801).

The fallacy of the trial court's analysis is that it required petitioner to prove to the court at the *Daubert/Wilt* hearing that diesel exhaust causes multiple myeloma. Even a cursory view of the well-settled law discussed above demonstrates that the trial court's analysis was incorrect. There is no magic number of epidemiologic studies needed to permit an expert to opine on a causal relationship[20]. To be sure, as the various courts that have reviewed the issue have concluded an expert can make a causalty determination without epidemiologic evidence[21]. Additionally, while the trial court found otherwise, an elevated risk need not be statistically significant. Indeed, respondent's own expert testified that even if a study demonstrates an elevated risk that is not statistically significant, that study is still evaluated in the overall judgment analysis, and is considered "nonpersuasive positive. It is sort of a vote for causality but not a convincing one." (A.R. 635)[22]. *See also* Infante testimony. (A.R. 91-94). Finally,

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[19]Interestingly the trial court ignored the Infante testimony explaining that assertion is outdated, and that numerous researchers have demonstrated a relationship between benzene and multiple myeloma, including Dr. Infante's own meta-analysis of various benzene studies, as well as the President's Cancer Panel's 2010 findings that there is strong evidence of an association between benzene and multiple myeloma. (A.R. 139-140).

[20]Indeed in the *King* case, discussed *infra*, the plaintiff's expert relied on one study.

[21]Here petitioner's experts explained the epidemiology that supported their opinions. The trial court simply disagreed that the data was sufficient to use in a causality determination relying on Dr. Shields' testimony.

[22]Dr. Phillip Cole, a noted epidemiologist, was retained by the respondent. He did not testify live at the hearing, but petitioner introduced his deposition. (A.R. 616-647).

petitioner's introduced a recognized treatise on cancer epidemiology which recognized the relationship between exhaust and multiple myeloma[23]. (A.R. 334-335). Although the evidence was contradictory, petitioner's evidence was more than sufficient to present a factual question as to causation[24].

2. Trial court's findings regarding the applicability of animal studies.

Petitioner's expert witnesses relied on animal studies to support there conclusions that Mr. Harris' exposure to diesel exhaust caused or contributed to his development of multiple myeloma. Those studies included animals that were exposed to PAHs (polycyclic aromatic hydrocarbons (a constituent of diesel exhaust)), coal tar, and diesel exhaust. Furthermore, the studies were used to demonstrate biological plausibility for the relationship between these similar toxic agents, their impacts on the animal model, and as support for petitioner's expert witnesses conclusions. (A.R. 24-40; 469). Indeed, petitioner's experts explained that mice developed plasmacytomas[25] after exposure to diesel exhaust which in petitioner's expert witnesses' opinions supports diesel exhaust's ability to cause multiple myeloma. (A.R. 469). Dr. Durie, a world

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[23]"Myeloma risk was related to a history of occupational exposure to diesel or engine exhaust in one cohort and six case-control studies." A. J. De Roos, et al., "Multiple Myeloma," in *Cancer Epidemiology and Prevention* 919, 939 (David Schottenfeld and Joseph F. Fraumeni, eds. 3d ed. 2006).

[24]Courts cannot exclude experts whose testimony falls within the range of matters about which reasonable experts can disagree. *See Milward*, 639 F.3d at 29-30 ("The court's analysis repeatedly challenged the factual underpinnings of Dr. Smith's opinion, and took sides on questions that are currently the focus of extensive scientific research and debate--and on which reasonable scientists can clearly disagree. In this, the court overstepped the authorized bounds of its role as gatekeeper. 'The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact.'") (citation omitted.).

[25]As indicated above, plasmacytoma is a single myeloma. *See* footnote 1, supra.

renowned expert in multiple myeloma, relied on his own clinical experience with patients who developed multiple myeloma, as well as a particular patient who developed multiple myeloma working with dolphins which also had developed multiple myeloma as further support for the causal relationship. (A.R. 470-471).

Nevertheless, the trial court, relying solely on the bold assertions of Dr. Shields made during the evidentiary hearing, concluded that "[a]nimal data does not assist in determining a causal association of cancer in humans." (A.R. 761, 778, 797). However, most courts have concluded just the opposite – animal data is admissible and helpful in determining causation. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 781 (animal studies pass *Daubert* muster, are admissible, and are one source by which plaintiffs can prove the harmful effects of PCBs); *Leake v. U.S.*, 843 F. Supp.2d 554, 560 (E.D. Pa. 2011) ("Animal studies may also provide sufficient scientific basis for an expert's general causation opinion, provided there are 'good grounds to extrapolate the findings from animals to humans.'") (internal citations omitted); *Metabolife Int'l, Inc. v. Wornick*, 264 F.3d 832, 842-43 (9th Cir. 2001) (animal studies not *per se* unreliable, and can "provide useful data about human health"); *McClellan v. I-Flow Corp.*, 710 F. Supp.2d 1092, (D. Ore. 2010) (expert witness' extrapolation from animal studies admissible, and "[w]hatever inadequacies arise from extrapolation will no doubt be addressed through vigorous cross-examination").

Additionally, the International Agency for Research on Cancer, an arm of the World Health Organization, labels a substance as a *probable human carcinogen* when at least two animal studies indicate a substance causes cancer. *See* IARC Monograph on the Evaluation of Carcinogenic Risks to Humans, Overall Evaluations of Carcinogenicity, Update of IARC

Monograph, Vols, 1-42, Supplement 7, International Agency for Research of Cancer, Lyon France, 1987; IARC Monographs on the Evaluation of Carcinogenesis Risks to Humans, Vols. 1-54, International Agency for Research on Cancer, Lyon France, 1972-1992. The National Toxicology Program uses animal data to determine if a substance is reasonably anticipated to be a human carcinogen. National Toxicology Program, *Listing Criteria*, Report on Carcinogens. (12th ed. 2011).

As such, the determination by the trial court that animal studies cannot support human cancer causality is against the well-settled law on the topic, and undermines the trial court's reasoning, conclusions, and decision[26].

3. Cross-examination fodder.

The trial court raised various issues which are certainly fodder for cross-examination, but even considered collectively do not make the petitioner's experts' opinions inadmissible. *See Gentry,* 195 W.Va. at 527, 466 S.E.2d at 186 (" '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence' "), *quoting Daubert,* 509 U.S. at 596, 113 S.Ct. at 2798, 125 L.Ed.2d at 484 (1993); *State v. Thomas,* 187 W.Va. 686, 691, 421 S.E.2d 227, 232 (1992) ("[c]ross-examination is the engine for truth").

Specifically, the trial court's memoranda found that cigarette smoke contains the same carcinogens as diesel exhaust (A.R. 764, 781, 800); U.S. EPA and the International Agency for Research on Cancer (IARC) have not identified the railroad industry as causing cancer or that

[26]As discussed below, at the very least animal studies combined with other data can support a causality determination.

diesel exhaust causes multiple myeloma (A.R. 763, 766, 799); no organization that practices good science has concluded that multiple myeloma is caused by diesel exhaust exposure (A.R. 766, 783, 802); an IARC Technical Bulletin which suggested a relationship between exhaust exposure and multiple myeloma did not express an IARC judgment on the topic and was not intended to make a causation statement (A.R.766,783, 802); many of the studies on which plaintiff's epidemiology expert relied demonstrated problems, and therefore could not act as a basis for a causal determination (A.R. 765-66, 782-83, 801-02); a lack of a dose-response in a study that purports to be positive for a causal association may be the result of chance alone[27]. (A.R. 762, 779, 798).

While these areas are available for cross-examination of petitioner's expert witnesses, they do not preclude the admissibility of their opinions. The trial court once again simply accepted the respondent's expert witnesses' assessments and conclusions as correct, and ignored petitioner's expert witnesses' testimony on the topics.

B. Other Courts Have Rejected the Analysis Utilized by the Trial Court.

Unfortunately, the trial court conducted its analysis of the admissibility issue in the present case almost exactly as the state district court had done in *King v. Burlington Northern Santa Fe Railway Company*, 277 Neb. 203, 762 N.W. 2d 24 (2009). In *King*, the plaintiff asserted that his development of multiple myeloma resulted from his exposure to diesel exhaust while employed by the Burlington Northern Sante Fe Railway Company. As in this situation, the railroad contended through the same expert, Dr. Peter Shields, that the causes of myeloma are

[27]Dr. Cole indicated that a lack of a dose-response in an epidemiology study does not prevent the study from supporting causality. (A.R. 633).

unknown, and that the majority of the epidemiological studies failed to show that diesel exhaust can cause multiple myeloma. The district court granted a motion to exclude plaintiff's expert, Dr. Arthur Frank, "because the studies he relied on failed to conclusively state that exposure to diesel fuel exhaust causes multiple myeloma," 277 Neb. at 207, 762 N.W. 2d at 31, and that "his opinion was unreliable because it did not have general acceptance in the field." 277 Neb. at 210, 762 N.W. 2d at 33. The district court then granted the railroad's motion for summary judgment. Finding no abuse of discretion, the Nebraska Court of Appeals affirmed the district court's ruling. *King v. Burlington Northern Sante Fe Railway Company*, 16 Neb. Ct. App. 544, 746 N.W. 2d 383 (2008).

On appeal, without determining whether Dr. Frank relied on sufficient studies or utilized a proper methodology in coming to his conclusion as to causation, the Nebraska Supreme Court reversed the Court of Appeals concluding that the district court had applied the wrong standard of review. In doing so, the Supreme Court noted Dr. Shields' opinion was simply that there are too few studies showing a positive association to support a causation conclusion[28]. Naturally, Dr. Frank disagreed. 277 Neb. at 210, 762 N.W. 2d at 33. Citing the causation standard in a FELA case ("an employee must present expert testimony evidence supporting an inference that the employee's injuries were caused by exposure to the substance attributable to the railroad's negligent act or omission"), the Court concluded that "when an expert bases his or her opinion on a reliable methodology, a court should not exclude it solely because a disagreement exists between the parties' qualified experts." 277 Neb. at 225, 762 N.W. 2d at 42 *citing Epp v. Lauby*,

[28]Dr. Frank had relied on one study that showed a significant association between diesel exhaust and multiple. 277 Neb. at 210, 762 N.W. 2d at 33.

271 Neb. 640, 715 N.W.2d 501 (2006) (noting that the district court did not have the benefit of decision when it made its ruling). "[A] trial court should not require general acceptance of the causal link between an agent and a disease or condition if the expert otherwise bases his or her opinion on a reliable methodology." 277 Neb. at 228, 762 N.W. 2d at 44. "In short, the significance of epidemiological studies with weak positive associations is a question of weight, not admissibility." 277 Neb. at 232, 762 N.W. 2d at 47.

Petitioner would maintain that the correct analysis of the present issues is found in the *King* decision, and when applied to the case at bar requires a reversal of the trial court's rulings. However, during the evidentiary hearing, respondent offered the trial court a copy of the Arkansas appellate court decision of *Richardson v. Union Pacific R.R. Co.*, 2011 Ark. App. LEXIS 602 (Ark. Ct. App. 2011), which the trial court referenced in its findings of fact and conclusions of law. The *Richardson* case warrants little weight here, however. Initially, the *Richardson* court applied Arkansas law, which differs substantially from West Virginia law. To be sure, that court expressly disagreed with a line of Nebraska cases (including *King v. Burlington Northern Santa Fe Railway Co.*, *supra*) that are in line with West Virginia authority on the subject, noting that those cases "are not in accord with federal precedent based on Arkansas law." 2011 Ark. App. LEXIS 602 at 48.

One of the primary reasons the *Richardson* court excluded the expert testimony at issue there was those experts' failure to quantify the plaintiff's exposure to the chemicals in question. *See*, 2011 Ark. App. LEXIS 602 at 60. Arkansas has adopted the requirement that a toxic tort plaintiff prove the frequency, regularity, and proximity of his or her exposures in order to recover. *Chavers v. GMC*, 79 S.W.3d 361, 369 (Ark. 2002). No such rule exists in West

Virginia.

Moreover, and perhaps more importantly, the *Richardson* court reviewed the trial court's evidentiary rulings under the deferential abuse of discretion standard. 2011 Ark. App. LEXIS 602 at 3. The issue in this case, on the other hand, is subject to *de novo* review. *In re Flood Litig. Coal River Watershed*, 222 W.Va. at 580, 668 S.E.2d at 209. Put simply, this Court is empowered to overturn the trial court's ruling for far less grave error than what would have required reversal in *Richardson*.

Additionally, the opinions of the petitioner's experts here do not suffer from some of the flaws that the *Richardson* court cited in barring the experts in that case from testifying. For instance, as noted above, the *Richardson* court identified the lack of a quantification of the plaintiff's chemical exposures as a primary reason for excluding the experts' testimony. Here, on the other hand, the trial court did not criticize the petitioner's experts' understanding of the exposures in question, and the respondent did not raise "exposure" quantification as an issue of concern.

C. Petitioner's Expert Witnesses' "Weight-of-the-Evidence" Approach.

As demonstrated above, petitioner's expert witnesses reliably applied a "weight of the evidence" methodology which employed the Bradford-Hill viewpoints that has been utilized by IARC, U.S. EPA, and industry. They reviewed the relevant literature (both epidemiologic and animal), the level of diesel exhaust as well as benzene exposure; they considered the toxic similarities between diesel exhaust, PAHs and coal tar; they considered Mr. Harris' clinical presentation; and concluded that Mr. Harris' exposure to diesel exhaust caused or contributed to his development of multiple myeloma.

Petitioner's expert witnesses' approach was recently approved in the First Circuit's *Milward* decision discussed above. In reversing a lower court's exclusion of expert witness testimony on causation in a toxic tort case, the *Milward* court acknowledged certain shortcomings in the relevant epidemiological literature, but found "the accumulation of multiple scientifically acceptable inferences from different bodies of evidence" sufficiently reliable to support an admissible expert opinion. 639 F.3d at 38. Rather than elevating any one factor to the status of a *sine qua non* for admissibility, the *Milward* court permitted an expert witness to testify where "the sum of his testimony was that a weighing of the Hill factors, including biological plausibility, supported the inference that the association between [the exposure and the disease at issue] is genuine and real." *Id.* at 39. The same can be said of the petitioner's expert witnesses here.

In the final analysis, this case simply involved two groups of well-qualified expert witnesses reviewing the same data, and coming to different conclusions. As respondent's epidemiologist testified:

> Q. So if – if a scientist did what you did; identified the studies, looked at positives and negatives, look at specificity, looked at strength and association, looked at dose for dose response and then made his subjective professional judgment, as Dr. Cole and Dr. Infante say, that would be appropriate?
>
> A. Yeah. Well, I think in this case, scientists have.
>
> Q. And if other scientists did that, that would be appropriate too, correct?
>
> A. Again, based on a transparent, accessible framework, yes.

Shields' testimony. (A.R. 225).

Petitioner's experts did exactly what in Dr. Shields' opinion is appropriate methodology for determining causation. These dueling experts reviewed the same data and came to different conclusions. The fact that both groups of experts reached diametrically opposed conclusions is not surprising, since "most of the cases in which expert testimony is offered involve only qualified experts disagreeing about the interpretation of data that was obtained through standard methodologies[.]" *Walker*, 221 W.Va. at 564, 655 S.E.2d at 780.

The opinions of the petitioner's experts do not suffer from the flaws suggested by the trial court. Indeed, in arriving at their opinions, petitioner's expert witnesses employed the same level of intellectual rigor that characterizes the practice of an expert in their relevant fields, as required by West Virginia law. Furthermore, since the role of the court is not to search the record for conflicting circumstantial evidence and to take the case from the jury because the evidence equally supports inconsistent and uncertain inferences, the quibbles over every detail of the scientific literature relied on by petitioner's experts in an attempt to elevate cross-examination fodder into grounds for exclusion is misguided, and against the weight of well-settled law.

CONCLUSION

Because a complete review of the hearing transcripts and the evidence introduced fails to support a finding that the petitioner's expert witnesses' opinions are unreliable, the rulings of trial court should be reversed with instructions on remand that since petitioner's expert witnesses' methodology was appropriate their testimony is admissible.

Signed:

R. Dean Hartley (WV Bar # 1619)
Counsel of Record for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of December, 2012, true and accurate copies of the foregoing Petitioner's Brief were deposited in the U.S. Mail contained in a postage-paid envelope addressed to counsel for all other parties to this appeal as follows:

Counsel for Respondent

James W. Turner, Esq.
STEPTOE & JOHNSON, PLLC
Chase Center - Second Floor
1000 Fifth Avenue, Suite 250
Huntington, WV 25701

Signed:_____

R. Dean Hartley (WV Bar # 1619)
Counsel of Record for Petitioner