

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE
IN AND FOR NEW CASTLE COUNTY

ANAJAI CALCAÑO PALLANO, et al.,))	
)	
Plaintiffs,))	
)	
v.))	C.A. No. N09C-11-021 JRJ
)	
THE AES CORPORTATION, et al.,))	
)	
Defendants.))	

ORDER

AND NOW TO WIT, this 7th day of December, 2015, the Court having heard and duly considered AES’s *Daubert* Motion No. 1 to Exclude the Testimony of Dr. Cynthia Bearer;¹ Plaintiffs’ Response to AES’s *Daubert* Motion No. 1 to Exclude the Testimony of Dr. Cynthia Bearer;² and AES’s Reply;³ **IT APPEARS THAT:**

¹ AES’s *Daubert* Motion No. 1 to Exclude the Testimony of Dr. Cynthia Bearer (“Defs.’ Mot. Exclude Dr. Bearer”) (“Trans. ID. 57345327). This Motion is one of nineteen *Daubert* Motions filed by the parties. Defendants have challenged seven of Plaintiffs’ causation experts and four of Plaintiffs’ exposure experts. Plaintiffs have challenged six of Defendants’ causation experts and two of Defendants’ exposure experts. The parties submitted twenty-six Joint *Daubert* Exhibits, which include each expert’s report, deposition, and curriculum vitae (“J. Ex.”) (Trans. ID. 57342400). *See* J.Ex. 1.A Cynthia F. Bearer, M.D., Ph.D. Expert Report (“Dr. Bearer Expert Report”). Dr. Bearer’s expert report is fifty-one pages containing 180 paragraphs and her Affidavit submitted in response to Defendant’s Motion to Exclude is forty-two pages containing 139 paragraphs.

² Plaintiffs’ Response to AES’s *Daubert* Motion No. 1 to Exclude the Testimony of Dr. Cynthia Bearer (“Pls.’ Resp.”) (Trans. ID. 57496471).

³ AES’s Omnibus Reply in Support of *Daubert* Motions No. 1, 2, 3 and 4 to Exclude Drs. Bearer, Mattison, Khattak and Finnell (Trans. ID. 57607790).

1. Plaintiffs' expert Dr. Cynthia Bearer received a doctoral degree in biochemistry from Case Western Reserve University, a degree in medicine from The Johns Hopkins University, and is board certified in pediatrics and neonatal-perinatal medicine.⁴ Dr. Bearer serves as the Mary Gray Cobey Professor of Neonatology and Chief of the Division of Neonatology at the University of Maryland School of Medicine.⁵ Dr. Bearer's clinical practice includes caring for newborns with birth defects, and an essential part of her clinical practice is researching and interpreting scientific literature about human growth and development and the effect of hazardous and toxic exposure to humans and laboratory animals.⁶

2. For over twenty years, Dr. Bearer has studied fetal neurotoxicity of heavy metals, ethanol, and other volatile organic chemicals.⁷ She has published many peer-reviewed articles and peer-reviewed abstracts relating to this topic.⁸ Dr. Bearer is currently conducting research measuring premature infants' exposures to heavy metals and correlating the exposures with the infants' cognitive

⁴ Dr. Bearer Expert Report ¶ 1.

⁵ *Id.* ¶ 3.

⁶ *Id.* ¶¶ 3–4.

⁷ *Id.* ¶¶ 4–5; Pls.' Resp., Ex. A Dr. Bearer Affidavit ¶¶ 7–8 ("Dr. Bearer Aff.").

⁸ *See* Pls.' Resp., Ex. B Dr. Bearer Curriculum Vitae. Dr. Bearer's CV lists sixty-five peer reviewed publications relating to the mechanisms of damage to the developing brain and the neurotoxicity of heavy metals including arsenic, cadmium, mercury, manganese, nickel, and lead.

outcomes at one, two, and three years of age.⁹ Dr. Bearer is also researching the indoor air quality of isolettes (in which premature infants spend weeks to months) and premature infants' exposures to volatile organic chemicals from the air within the isolette.¹⁰

3. Defendants seek to exclude Dr. Bearer's opinions that: (1) Coal Ash Waste causes structural birth defects in humans and neurotoxic damage in developing humans; and (2) the Coal Ash Waste at issue caused each Plaintiffs' specific injuries.¹¹

4. In *Tumlinson v. Advanced Micro Devices, Inc.*¹² and *Anderson by Anderson v. ATMI, Inc.*,¹³ the plaintiffs alleged that occupational chemical exposure at semiconductor factories caused birth defects in their children. In both cases, the Court excluded Dr. Bearer's expert opinion—that an adult's exposure to clean room chemicals caused their child's birth defects—because Dr. Bearer did not adequately detail her methodology.¹⁴ Here, Defendants do not challenge

⁹ Dr. Bearer Expert Report ¶ 6.

¹⁰ *Id.* ¶ 7.

¹¹ See *Pallano, et al. v. AES Corp., et al.*, C.A. No. N09C-11-021 JRJ, November 24, 2015 Opinion Denying Defendants' *Daubert* Motion to Exclude the Testimony of William P. Konicki. The Court incorporates by reference the facts, background, and the discussion of Delaware Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), set forth in that opinion.

¹² *Tumlinson v. Advanced Micro Devices, Inc. (Tumlinson II)*, 2013 WL 7084888 (Del. Super. 2013) *aff'd*, 81 A.3d 1264 (Del. 2013).

¹³ *Anderson by Anderson v. ATMI, Inc. (Anderson I)*, 2014 WL 603254 (Del. Super. Feb. 5, 2014); *Anderson II*, 2014 WL 1266839 (Del. Super. Mar. 26, 2014).

¹⁴ *Tumlinson II*, 2013 WL 7084888, at *11–13 (“[B]oth [Bradford-Hill Criteria and the weight-of-the-evidence] methods require the scientist to articulate her thought process, evaluation

Dr. Bearer’s qualifications, but argue that her methodology suffers from the same “analytical gaps” that rendered her opinions inadmissible in *Tumlinson* and *Anderson*. The Court wholly disagrees.

5. In this case, Dr. Bearer opines to a reasonable degree of medical probability that Coal Ash Waste causes structural birth defects in humans and neurotoxic damage in developing humans.¹⁵ To reach this general causation opinion, Dr. Bearer utilized the Bradford-Hill Criteria and the weight-of-the-evidence analysis.¹⁶ Dr. Bearer’s report explains the science of epidemiology and epidemiological studies, the Bradford-Hill Criteria, and weight-of-the-evidence

methods, and conclusions to establish reliability.”). In *Tumlinson*, the Court held that there were too many “analytical gaps” between Dr. Bearer’s proffered opinion and the data she relied upon, rendering her opinion inadmissible under *Daubert*. *Id.* at *1. The Court reasoned that Dr. Bearer’s opinion: (1) was not peer reviewed; (2) “lack[ed] the specificity of chemicals, exposure, or doses necessary to be testible [sic];” (3) “piece[d] together epidemiology, animal studies, *in vivo* studies, and *in vitro* studies that examine[d] tangential exposures and harms without any explanation as to the relative weight each study deserve[d];” and (4) “applie[d] established methods, like dose-response, in novel ways, again without necessary explanation.” *Id.* Similarly, in *Anderson*, the Court held that Dr. Bearer did not “adequately articulate her thought process, evaluation methods, and conclusions to establish reliability,” and the studies Dr. Bearer relied upon did not support her opinion or “fit” the case. *Anderson I*, 2014 WL 603254, at *2. The Court reasoned that, similar to *Tumlinson*, Dr. Bearer cited “studies involving other chemicals and other injuries (not suffered by the minor plaintiff []), and attempt[ed] to make it all ‘fit’ by invoking general ideas about oxidative stress.” *Anderson II*, 2014 WL 1266839, at *1.

¹⁵ Dr. Bearer Expert Report ¶¶ 45, 96.

¹⁶ The Bradford-Hill Criteria and the weight-of-the-evidence analysis are two methods routinely used by epidemiologists to establish causation, and routinely used in Dr. Bearer’s professional practice as a researcher and clinician. *See Tumlinson v. Advanced Micro Devices, Inc.*, 81 A.3d 1264, 1272 (Del. 2013). “The Bradford–Hill factors permit epidemiologists to infer a causal relationship from an association of variables, which include: (1) temporal relationship, (2) strength of relationship, (3) dose-response relationship, (4) replication of the findings, (5) biological plausibility, (6) consideration of alternative explanations, (7) cessation of exposure, (8) specificity of the association, and (9) consistency with other knowledge.” *Id.* In contrast, “[t]he weight-of-the-evidence [analysis] . . . allows an expert to fit all the sources together like a puzzle.” *Id.* (internal quotations omitted).

analysis, including principles for evaluating epidemiological studies.¹⁷ In explaining her methodology, Dr. Bearer provides a detailed description of how she researched and evaluated peer-reviewed literature, with a focus on empirically tested results from epidemiology, toxicology, and medical publications.¹⁸

6. With respect to Dr. Bearer's general causation opinion that Coal Ash Waste is capable of causing structural birth defects, Dr. Bearer carefully and thoroughly details all the research she relied upon, including: (1) coal mining pollution literature; (2) arsenic studies (human and animal); (3) lead studies (human and animal); (4) manganese studies (human and animal); (5) mercury studies (human and animal); (6) selenium studies (human and animal); (7) polycyclic aromatic hydrocarbons (PAHs) studies (human and animal); and (8) research relating to oxidative stress as a mechanism of causing structural birth defects and specific studies linking oxidative stress to coal pollution, fly ash, heavy metals, and PAHs.¹⁹ Dr. Bearer concludes her analysis of this research by summarizing her application of the Bradford-Hill Criteria.²⁰

7. With respect to Dr. Bearer's general causation opinion that Coal Ash Waste causes neurotoxic injuries, Dr. Bearer, again, carefully and thoroughly details the research she relied upon, including: (1) coal ash literature; (2) arsenic

¹⁷ Dr. Bearer Expert Report ¶¶ 14–44.

¹⁸ Dr. Bearer Aff. ¶ 10; Dr. Bearer Expert Report ¶ 45.

¹⁹ Dr. Bearer Expert Report ¶¶ 46–84.

²⁰ *Id.* ¶¶ 85–95. Dr. Bearer concludes, “criterion met” with respect to every factor of the Bradford-Hill Criteria. *Id.*

studies (human and animal); (3) lead studies (human and animal); (4) inorganic mercury studies (human and animal); (5) manganese studies (human and animal); and (6) PAHs studies (human and animal).²¹ Dr. Bearer concludes her analysis of this research by summarizing her application of the Bradford-Hill Criteria.²² Again, Dr. Bearer concludes, “criterion met” with respect to every factor of the Bradford-Hill Criteria.²³

8. Dr. Bearer performed a differential diagnosis to establish specific causation.²⁴ Dr. Bearer’s specific causation opinion proceeds injury-by-injury and toxin-by-toxin, and discusses alternate causes.²⁵ Dr. Bearer addresses epidemiologic studies relating to the toxic effects of coal mining pollution, studies related to the toxic effects of the individual Coal Ash Waste constituents, and how these studies factor into her analysis for each Plaintiff.²⁶ For example, with respect to minor Plaintiff Isael’s vertebral anomaly, Dr. Bearer explains why she relied upon the 2011 Ahern epidemiological study, which found “that musculoskeletal

²¹ *Id.* ¶¶ 96–117.

²² *Id.* ¶¶ 118–28.

²³ *Id.*

²⁴ *Bowen v. E.I. Du Pont De Nemours & Co.*, 2005 WL 1952859, at *10 (Del. Super. 2005) (“In order to establish the cause of a condition, an expert must not only be able to state the cause of a condition, the witness, or the party offering the testimony, must also be able to exclude other possible/putative causes. In scientific circles, this is known as performing a differential diagnosis. It is a commonly accepted method of addressing the issue of the origin or cause of a medical condition.”).

²⁵ Dr. Bearer Expert Report ¶¶ 129–80; Dr. Bearer Aff. ¶¶ 18–135.

²⁶ *Id.*

defects were increased in communities affected by coal mining pollution.”²⁷ Dr. Bearer also identified seven studies finding that exposures to arsenic, lead, and selenium cause certain vertebral anomalies consistent with Plaintiff Isael’s injuries.²⁸ In addition to analyzing over 180 epidemiology, toxicology, and medical publications, Dr. Bearer reviewed and relied upon historical exposure data and expert exposure models to evaluate the timing, length, and intensity of exposures.²⁹

9. Dr. Bearer’s opinions pass muster under D.R.E. 702 and *Daubert*. Dr. Bearer’s proffered testimony is based upon sufficient facts and data,³⁰ is the product of reliable principles and methods, and she has applied the principles and methods reliably to the facts of this case. Dr. Bearer has explained the literature she relied upon (and did not rely upon), the methodology she employed, and has articulated her thought process, evaluation methods, and conclusions.

²⁷ Dr. Bearer Aff. ¶¶ 43–63.

²⁸ *Id.* ¶ 58.

²⁹ *Id.* ¶¶ 110–27.

³⁰ Dr. Bearer’s opinions are supported by peer-reviewed and tested literature, her personal examination of the living Plaintiff children, her review of the Plaintiffs’ clinical and examination reports and neuropsychological evaluations. Pls.’ Resp. at 9–11.

WHEREFORE, because the Court finds that the opinions set forth in Dr. Bearer's Expert Report, Deposition, and Affidavit are both relevant and reliable, the Defendants' Motion to Exclude is **DENIED**.

IT IS SO ORDERED.

Jan R. Jurden, President Judge