

IN THE SUPREME COURT OF THE STATE OF DELAWARE

WENDOLYN TUMLINSON, JAKE ALBERT)
TUMLINSON, JILLVEH ONTIVEROS and) No.: 672,2012D
PARIS ONTIVEROS by her mother and next friend)
JILLVEH ONTIVEROS,)
) Appeal from the Superior Court
Plaintiffs Below, Appellants,) of the State of Delaware in and for
) New Castle County
-vs.-)
) C.A. No. 08C-07-106 FSS
ADVANCED MICRO DEVICES, INC.,)
)
Defendant Below, Appellee.)

PLAINTIFFS BELOW—APPELLANTS’ OPENING SUPPLEMENTAL MEMORANDUM

In 2012, the motion Court praised Linda Frazier M.D. M.P.H.’s credentials, scholarship, and experience.¹ Although it excluded her under a misapplication of Texas law, the motion Court also recognized that *Daubert*² is more liberal. Accordingly, when this Court directed it to evaluate reliability under Delaware law, exclusion seemed unlikely given Dr. Frazier’s careful analysis, supported by extensive toxicological, epidemiological, government, and industry studies.

Nonetheless, the remand Court excluded Dr. Frazier. Before addressing that Court’s many errors, the record in this action deserves emphasis. It includes:

- a. Four highly credentialed physicians and scientists collectively and individually finding causation (A470-866; A1538-48). Two highly credentialed experts also quantified exposure, corroborating AMD’s data (A966-1035; A1063-94);

¹ *Tumlinson v. Advanced Micro Devices, Inc.*, 2012 Del. Super. LEXIS 209, *12-13 (Del. Super. Ct. Jan. 6, 2012).

² *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993)(“*Daubert*”).

- b. Evaluation of extensive medical records to identify Jake and Paris' true malformations (A740-7; A477-82; A607-10);
- c. Toxicological proof demonstrating that ten exposure chemicals cause birth defects (A669-86), including a consensus that ethylene glycol ethers ("glycol ethers") are reproductively toxic at vanishingly small exposures. A642-45; A1174-5; A751. Peer-reviewed animal (A1174; A292-4; A488-9; A495-7) and human (A510; A514; A517; A519; A1036) studies have consistently demonstrated their capacity to produce reproductive harm, including Plaintiffs' very birth defects. Government and industry studies, and NIOSH and CAL-OSHA warnings, are also in accord (A830-44; A1095-1154);
- d. Analysis demonstrating that the parents' glycol ether exposures at AMD exceeded levels documented to cause harm (A1474-80; A749-63; A794-811; A1542-4);
- e. Proof that, since the early 1980s, AMD disregarded scientific literature, federal and state warnings, chemical manufacturer warnings, and studies conducted on behalf of its industry. Undeterred, AMD continued to wrongfully expose and mislead Plaintiffs (A816-66; A748-74; A788-811);
- f. Multiple studies of the semiconductor industry, *including studies evaluating AMD's facilities*, consistently finding that semiconductor work causes spontaneous abortion at exposure levels comparable to or lower than those at AMD, and the studies of Drs. Lin and Sung, which associated such work with Paris' heart anomalies (A488-550; A1036-40; A627-56);
- g. Careful ruling out of alternate causes (A774-77; A811-14);
- h. Thorough explanation of the Bradford-Hill (A567-72; A1158-78; A1381-90), weight-of-the-evidence (A564-7), and differential diagnosis methods employed (A591-93; A699-703);
- i. Extensive peer-reviewed literature demonstrating that:

1. The causation chemicals all inflict reproductive harm in animals (A1174; A488-506; A1255);
 2. Chemicals utilized at AMD inflict reproductive harm in humans (A509-49; A289-290);
 3. The causation chemicals can cause Jake and Paris' injuries (A1164-7; A1036-40; A1174-6; A488-549);
 4. The parents' semiconductor work causes spontaneous abortions and birth defects, including Paris' heart anomalies (A1036-40; A244-58; A509-49);
 5. A majority of spontaneous abortions are caused by malformations lethal to the fetus (A589; A606; A1245);
 6. Toxic exposures causing spontaneous abortions are higher than exposure levels causing birth defects (Id.; A1241; A1247; A1249);
 7. Maternal obesity without diabetes is not associated with birth defects (A775-77);
- j. Application of proper methods to the record, explaining where pieces of proof fit in the causal chain, with emphasis on particularly salient studies. A1381-90; A470-739; A1155-90.

Against that showing, this memorandum explains why the ruling below was an abuse of discretion, was wrongly decided, and is contrary to Delaware law.

ARGUMENT

The remand decision requires reversal for two fundamental reasons. First, in repeatedly misapprehending the evidence, failing to engage with key parts of the record, and making incorrect factual assertions, the Court abused the discretion it possessed. Second, by incorrectly viewing this as a case of first impression, the

Court departed from Delaware's settled liberal *Daubert* law, repeatedly inserting *dicta* which, if endorsed, would transform gatekeepers into goalkeepers, and gates into pin holes, through which it would be virtually impossible for meritorious claims to pass. The motion Court repeatedly nods in the direction of existing law, and then proceeds to advance reasons why a more cramped analysis should supplant this Court's clear directive that cross-examination, not preclusion, is best.

I. MATERIAL ERRORS AND OVERSIGHTS WARRANT REVERSAL

This Court reviews "findings of fact 'to determine if they are supported by the record and are the product of a logical and orderly reasoning process.'"³ Here, the motion Court repeatedly and improperly disregards and fails to consider many material facts, rendering its decision a clear abuse of discretion.

First, with respect to Dr. Lin's critical study, the remand Court notes that Lin drew the required association between paternal clean room exposures and Paris' cardiac anomalies, with odds ratio well over 2, and good statistical power. A1036-40. It then takes leave of the record to find incorrect reasons to criticize Lin. Thus, it wrote that there is no showing that Lin studied exposures comparable to the parent Plaintiffs'. This ignores sworn proof from Dr. Stewart, *a technical*

³ *GMC v. Grenier*, 981 A.2d 524, 527-28 (Del. 2009)(citation omitted). As Plaintiffs' opening brief relates, decisions properly applying Delaware law to expert testimony are ordinarily reviewed for abuse of discretion. *M.G. Bancorporation v. Le Beau*, 737 A.2d 513, 522 (Del. 1999). However, *de novo* review is necessary "[t]o the extent that the claim of error implicates questions of law[.]" *Holden v. State*, 23 A.3d 843, 846 (Del. 2011)(citation omitted).

consultant to Dr. Lin, confirming substantial similarity of exposure. A1530-37.⁴

The Court also criticizes Lin for failing to address live offspring. Yet, it was undisputed that, by excluding live children with birth defects from his numerator, but including them in his denominator, Dr. Lin *understated* his findings. Any live child with a heart anomaly, born to a semiconductor father, would only elevate the odds ratio from Lin's astronomical findings exceeding 4.0. A1036-40; A1364-66.

Simply put, Dr. Lin's study alone satisfies every reliability criticism (peer-reviewed, same occupation, same exposure, same adverse outcome, statistical significance, and odds ratios well over two). It compels a determination that Dr. Frazier is reliable respecting Ontiveros as to both general and specific causation, since it is far more likely than not that Paris' malformations were caused by her father's exposures than any other possible source. Even the *Havner* Court accepted that approach. The contrary finding below exhibits a clear abuse of discretion.

Second, the Court suggests that exposure was not quantified. While precise quantification is not always possible or required,⁵ here Dr. Frazier analyzed exposure using AMD's data. A748-53; A790-800. James Stewart Ph.D. quantified

⁴ Nor is there any merit to the dismissal of Lin's study as "foreign," which is immaterial. Lin's article was peer-reviewed in an American journal, and accompanied by uncontradicted proof that it studied exposures substantially similar to the Ontiveros case. A1530-37.

⁵ *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1059-60 (9th Cir. 2003); *Kristensen v. Spotnitz*, 2011 U.S. Dist. LEXIS 107027, *11 (W.D. Va. Sept. 21, 2011). See also *New Haverford P'ship v. Stroot*, 772 A.2d 792, 799-800 (Del. 2001)(foundation does not require "precision of a laboratory experiment"). Any notion that Dr. Frazier failed to identify the pertinent chemicals is also incorrect. A483-84; A1185-86.

exposure using accepted industrial hygiene methods. A966-1035. Scott Reynolds P.E. also did so using computational fluid dynamics principles. A1063-94.

Third, the Court asserts, without support, that using vapor concentrations to assess exposure, or considering dermal exposures, is error. Accepted principles of industrial hygiene, reflected in regulations and peer-reviewed studies, measure exposure in that fashion. *E.g.*, A966-1035; A908-9; A914. Evaluating peak or dermal exposures is also proper. Dermal exposure is well known to introduce toxins into the bloodstream more rapidly than inhalation. A756-57. It is likewise well accepted that even a single high dose of toxin is capable of producing malformations. A750; A1018-19.

Fourth, the Court criticizes Dr. Frazier for developing conclusions for litigation. That generic complaint could be leveled against virtually any expert. Moreover, three prominent expert physicians and scientists endorsed Dr. Frazier's opinions in the Joint Affidavit, several of whom have published on reproductive hazards in the subject industry and/or chemicals at AMD. A817; A554-64. The criticism likewise ignores extensive peer-reviewed literature as to reproductive toxicity of clean room exposures, including government studies, and specific

chemicals to which Plaintiffs were exposed, including glycol ethers. E.g., A893-953; A217-321; A1095-1131.⁶

Fifth, the Court mischaracterizes Dr. Frazier's discussion of dose-response as "novel." In fact, her explanation that greater toxic exposures produce spontaneous abortion, while lesser exposures allow fetuses to survive with malformations, is well accepted. Plaintiffs provided peer-reviewed studies and texts to the Court on this point. A1234-69. It does not mention these studies.

Sixth, the Court suggests that there must be a "consensus" that chemicals are toxic. Far from requiring "consensus," *Daubert* rejected *Frye's* general acceptance approach.⁷ Moreover, there exists consensus here, particularly with respect to glycol ethers. Reproductive toxicity of cleanroom work is also well established in studies conducted on behalf of this industry, and not for litigation. A893-952.

Seventh, the Court accuses Dr. Frazier of failing to explain how she reached her conclusions. This overlooks Dr. Frazier's affidavit, which painstakingly refutes AMD's critique item by item. A1155-89. A joint expert affidavit then addresses

⁶ The motion Court also mistakenly suggests that the Digital epidemiological study found a slight positive association between clean room work and reproductive harm. In fact, it found relative risks exceeding 2.0. A551; A511-12. It likewise errs in writing that the IBM or JHU study does not support birth defect causation. The text of the IBM/JHU study recites that it did not look for that outcome. However, the data reveals that birth defects at IBM were elevated. A550; A898.

⁷ 509 U.S. at 589. Insofar as the remand decision excluded Dr. Frazier because the Plaintiffs do not have "signature" injuries, it also erred. Such injuries (*e.g.*, asbestos/mesothelioma) are rare. The cases cited in the remand decision confirm that, even there, litigants frequently assert controversy respecting whether particular products cause harm. *E.g.*, *GMC v. Grenier*, 981 A.2d 531 (Del. 2009). Most toxins produce injuries which can otherwise occur. The fact that lung cancer can be caused by other factors hardly means that experts should be excluded if they opine that decades of smoking substantially contributed to a party's developing lung cancer.

methodology at length, explaining the role of different types of evidence (*e.g.*, animal studies demonstrating chemicals' capacity to cause harms and biological plausibility; experiments examining the mechanisms of harm; and epidemiology studying workplace exposures and chemical exposures). A551-607. Dr. Frazier and her colleagues identified items of evidence, where they fit in the chain of causal reasoning (*e.g.*, whether they dealt with workplace exposures, specific chemicals, specific outcomes, humans, or animals), allowing a particularized appreciation of the roles of the many studies relied upon. A1380-91; A1155-89. Finally, Dr. Frazier cited studies and proofs (*e.g.*, Cordier, Lin, and the semiconductor studies) deserving emphasis, and lucidly explained her evaluation of the Hill criteria. *Id.*

Eighth, while noting that Jake and Paris suffer from multiple malformations, the Court uses misleading labels of VATER association and situs inversus. This overlooks uncontradicted testimony that actual injuries must be considered, not generalized "labels." A477-82. For instance, Jake suffers from multiple anomalies including spina bifida, renal malformations, and severe gastrointestinal defects. A746-47. Studies directly associate glycol ether exposure with multiple anomalies, and specifically with spina bifida, renal malformations, and gastrointestinal

defects. A282; A289; A1054-62; A495-502; A533; A547; A758; A777-78. The same is true of Paris' cardiac malformations. A509; A786-815; A1039.⁸

Ninth, the Court questions Dr. Frazier's explanation that cleanroom exposures produce multiple adverse outcomes. Yet, it is well known that cigarettes produce lung cancer, emphysema, hypertension, and stroke. Asbestos also causes mesothelioma, lung cancer, asbestosis, and pleural disease. As the record shows, this phenomenon is particularly present and well accepted in embryology, where the same insult will produce different injuries depending on gestational age, correlated with the stage at which organs are being generated. A601-03; A1238-40.

Tenth, the remand decision improperly rejects a wealth of non-epidemiological data, dismissing it out-of-hand because it comes from the "animal kingdom." Yet, as the Court is constrained to admit, even without epidemiology, animal, *in vitro*, and *in vivo* studies can support causation. Dr. Frazier identified myriad studies exposing animals to the causation chemicals at AMD, producing Paris and Jake's birth defects, including kidney defects, anal atresia, spina bifida, and heart defects, and explained her rationale for using these studies. A495-502; A1163-76; A1255-56; A1278. The Court likewise overlooked genotoxicity studies

⁸ Significantly, Paris' severe cardiac anomalies are disabling, and caused her to suffer a stroke with resultant worsening of disabilities. Like Lin's subjects, Paris' anomalies would have proved fatal but for skilled medical care. A786-87. The motion Court further overlooked Dr. Frazier's explanation of how damage to the parental genome can cause situs inversus. A813-14.

of humans, and *in vitro* comparisons of human and animal tissue, demonstrating the common harms these chemicals inflict on humans and animals. A503-6.

Eleventh, the Court rejects Dr. Frazier's differential diagnosis for failure to provide "an articulate methodical" exposition. To the contrary, Dr. Frazier expressly considers and rules out alternative explanations advanced by AMD. A774-78; A811-15. The remand decision cites no other "cause" overlooked by Frazier. Rather, it is reduced to saying that because there may be unknown causes that cannot be ruled out, a qualified physician's careful application of a well-accepted methodology fails under *Daubert*. The flaw in its reasoning is self-evident. Medicine is always evolving, and some causes of disease will be unknown. That hardly means that this methodology, on which physicians rely to make life and death decisions every day, is not reliable under *Daubert*. A605.

Twelfth, while finding Frazier competent to interpret pertinent literature, the remand Court dismisses her expertise as meaningless. Its repeated failure to credit a qualified and credible witness' thorough testimony, unchallenged by any defense expert, is inexplicable, and improperly invades the jury's province.

Thirteenth, the remand Court writes that there are too many "inferences" and "gaps" in Dr. Frazier's opinion, but spends little time identifying them, let alone

analyzing their shortcomings.⁹ As the foregoing analysis shows, when that Court did endeavor to identify failings, it misapprehended the facts. It is true that there are numerous factors to consider in this case (*e.g.*, the nature of the birth defects, the timing, duration, and intensity of the exposures, the capacity of the toxins to cause injury, and the absence of alternative explanations for the injury). Each of these must be considered in the light of established methodologies, and inferences must inevitably be drawn from animal, human, and experimental data in fields of medicine, epidemiology, toxicology and industrial hygiene. Since all of this was done, challenges to any link in the chain are for cross-examination, not preclusion. This is particularly true given Delaware's liberal *Daubert* jurisprudence, which the motion Court acknowledged, but did not apply.

II. Delaware's *Daubert* Jurisprudence Requires Reversal

The remand decision ostensibly rejects AMD's central legal argument, premised on *Havner*. Thus, it acknowledges that: a) one can opine on causation without epidemiology, b) Bradford-Hill criteria are proper, c) epidemiology studies with any positive association can be part of a reliable causation analysis, d) peer-

⁹ This absence of detail is in striking contrast with the detailed *Daubert* rulings addressing expert proofs. *E.g.*, *State v. McMullen*, 900 A.2d 103 (Del. Super. Ct. 2006); *Grenier v. GMC*, 2009 Del. Super. LEXIS 548 (Del. Super. Ct. Apr. 8, 2009); *Minner v. Am. Mortgage & Guar. Co.*, 791 A.2d 826 (Del. Super. Ct. 2000). In that regard, Plaintiffs cited fifteen material errors in the 2012 decision in their Opening Brief on appeal, pp.10-15. Despite raising them to the remand Court, its 2013 decision either ignores them or reiterates earlier mistakes. This includes repeating the erroneous finding that Dr. Sung did not report odds ratios, when he reported a *five-fold* increase in heart anomalies in male workers' offspring. A1041. A comparison of Plaintiffs' opening briefs, the record, and the decision on remand reinforces the failure of the motion Court to engage in a proper analysis.

review is not essential, e) epidemiological studies with a doubling of the risk can support specific and general causation, f) animal, *in vitro*, *in vivo*, and case studies are part of proper causation analysis, g) differential diagnosis alone is sufficient to support causal determinations, and h) a court must not serve as a “goalkeeper.”

These principles find broad support nationwide.¹⁰ Yet, despite noting them, the Court’s analysis departs from these precepts. As discussed, its “reliability” evaluation misconstrues or disregards key portions of the record. By deeming this case an issue of first impression, the decision also disregards Rule 702’s liberal thrust, and this Court’s admonition that “cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking [even] shaky but admissible evidence.”¹¹

Examples abound. To illustrate, the motion Court faults Dr. Frazier for not satisfying a “peer-review” test. In fact, her conclusions were grounded in extensive peer-reviewed literature, and also reviewed and endorsed by eminent scientists, as related above. E.g., A509-549. That critique also disregards the holding of *Daubert* and its progeny that peer-review and publication are merely pertinent

¹⁰ See, e.g., *GMC v. Grenier*, 981 A.2d 531, 539 (Del. 2009) (“there is no *a priori* requirement that an expert opinion be based on epidemiology in order to be admissible”); *Long v. Weider Nutrition Group, Inc.*, 2004 Del. Super. LEXIS 204, *18 (Del. Super. Ct. June 25, 2004)(same); *Milward v. Acuity Specialty Prods. Group*, 639 F.3d 11, 17-20, 23 (1st Cir. 2011)(reliance on “world-renowned epidemiologist Sir Arthur Bradford Hill’s” criteria was proper).

¹¹ *Tumlinson v. Advanced Micro Devices, Inc.*, 2013 Del. LEXIS 399, 17-18. n.52 (Del. Aug. 16, 2013)(quoting *Daubert*, 509 U.S. at 596). Delaware’s courts have addressed expert opinions founded upon epidemiology, differential diagnosis, and toxicological studies. See, e.g. n.10, *supra*. Dr. Frazier’s analysis, finding support in all these fields, is admissible under existing law.

considerations, and by no means required. 509 U.S. at 593-94.¹²

Similarly flawed is the motion Court's differential diagnosis analysis. It was constrained to admit that in Delaware, soundly performed differential diagnosis can independently support causation. *State v. McMullen*, 900 A.2d at 103. It also praises Dr. Frazier's experience in occupational medicine.¹³ Then, without basis, the motion Court substitutes its own judgment for qualified physicians' opinions. That ignores this Court's holding that "the asserted failure to eliminate other possible causes of plaintiffs' health problems" goes "to the weight of the experts' opinions, not their admissibility." *New Haverford P'ship v. Stroot*, 772 A.2d at 800. In any event, this is not a case in which an expert "utterly fail[ed] . . . to offer an explanation for why the proffered alternative cause was ruled out." *Clausen*, 339 F.3d at 1061 (citation omitted).¹⁴ Dr. Frazier methodically addresses every alternative cause. Her reasoning is not "circular," but the careful ruling out of alternative causes doctors routinely perform. A774-77, A1313-16.

¹² Reliance on *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995), which addressed FDA-approved Bendectin, was also misplaced. There, "[e]very published study here and abroad – and there have been many – conclude[d] that Bendectin is not a teratogen." *Id.* at 1314. On that record, the court found experts' inability to provide a single contrary article troubling, and affirmed a summary judgment ruling. *Id.* at 1318-21. This case presents the opposite scenario -- study after study, toxicological, epidemiological, *in vitro*, and *in vivo* have identified reproductive hazards of ethylene glycol ethers. See, e.g., A244-321, A487-550. Moreover, since *Daubert II*, myriad courts have reaffirmed that publication and peer-review are not essential. See, e.g., *Clausen v. M/V New Carissa*, 339 F.3d at 1056; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999); *King v. Burlington N. Santa Fe Ry. Co.*, 762 N.W.2d 24, 44 (Neb. 2009).

¹³ Drs. Bearer and Harrison are likewise highly qualified physicians. A554; A560.

¹⁴ Cf. *Minner*, 791 A.2d at 854 (expert failed to rule out a host of potential causes including smoking, alcohol use, obesity, depression, medication, and documented illnesses).

Tellingly, the remand Court cites no “cause” Dr. Frazier overlooked. Moreover, insofar as it disagrees with her conclusions concerning maternal diabetes, that is no basis for exclusion. Her findings are qualified, considered, and unchallenged by any contrary expert. Nor does the remand decision engage with Dr. Frazier’s explanation of multi-factorial etiology, whereby even if obesity were a predisposing factor, hazardous exposures at AMD were a concurrent proximate cause. A1316. In short, Dr. Frazier’s careful differential diagnosis was reliably performed, and AMD’s critique at most furnishes a basis for cross-examination.

The discretion *Daubert* affords a court is not license to disregard a record, substitute its own views for those of experts, and selectively pluck out-of-context snippets of testimony as an alternative to the whole record. Unfortunately, that is what occurred here. Delaware law does not support such a result.

III. The Sufficiency of Plaintiffs’ Claims are not Ripe for Resolution

On several occasions the motion Court, exceeding the remand’s parameters, asserts that Plaintiffs’ claims would prove insufficient under Texas law if Dr. Frazier is permitted to testify. However, no summary judgment motions have been made, let alone opposed. Moreover, even the remand decision recognizes that certain of the studies satisfy *Havner*. In the event that Dr. Frazier’s testimony is deemed admissible under Delaware law (as it should be), Plaintiffs respectfully request that they be afforded their basic and unquestioned right, which is to

respond to any summary judgment motion, and have it adjudicated impartially and without prejudgment on its own merits, using the familiar standard applicable to such motions.

To adopt AMD's atomistic approach, conflating admissibility with sufficiency, would alter the burden of proof and standard of review, and compromise Plaintiffs' constitutional rights. Insofar as it attempts to substitute Texas law for Delaware law, AMD also would undermine the rights of Delaware residents. They should be permitted to present meritorious claims without clearing thresholds this Court, and the remand Court, have rejected as unsound.

CONCLUSION

For the reasons stated herein and in Plaintiffs' earlier submissions, the order excluding Dr. Frazier should be reversed.

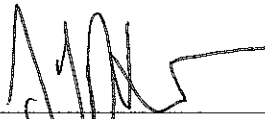
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