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IN THE SUPREME COURT OF THE STATE OF DELAWARE

Wendolyn Tumlinson, Jake Albert Tumlinson, Jillveh Ontiveros and Paris Ontiveros, by her natural mother and next friend Jillveh Ontiveros,	)	No.: 672,2012D
Plaintiffs Below, Appellants,	)	
v.	)	
Advanced Micro Devices, Inc.,	)	
Defendant Below, Appellee.	)	

PLAINTIFFS BELOW-APPELLANTS' OPENING BRIEF

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NATURE OF PROCEEDINGS

Plaintiffs-Appellants Jake Tumlinson ("Jake") and Paris Ontiveros ("Paris") have severe birth defects. Paris' father, Anthony Ontiveros, and Jake's mother, Wendolyn Tumlinson (collectively "the parents"), worked at semiconductor manufacturing facilities owned and operated by Defendant-Appellee Advanced Micro Devices, Inc. ("AMD").

Plaintiffs proffered experts highly qualified in fields including epidemiology, occupational medicine, hazard assessment, industrial hygiene, and biochemistry, including Linda M. Frazier, M.D., M.P.H. They opined that wrongful chemical exposures at AMD caused Jake's and Paris' injuries. Waiving its right to submit expert proofs, AMD moved to exclude Dr. Frazier. Plaintiffs opposed, submitting an affidavit from Dr. Frazier [A1155][1]; a lengthy affidavit from several experts [A470]; medical records; disclosure on the nature, intensity, and timing of exposures [*e.g.*, A483-486; A617-627; A686-698; A966-1035; A1063-1094]; proof of AMD's misconduct [*e.g.*, A197; A809-811; A821; A835-858]; and scientific literature. After a *Daubert* hearing [A1287], Plaintiffs proposed findings of fact and legal conclusions [A1549].

The Superior Court found Dr. Frazier qualified, and suggested that her opinions satisfied Delaware law. However, it excluded them by mistakenly applying Texas law, and misreading or overlooking evidence showing her testimony to be admissible in Delaware or Texas. Rather than conduct further hearings as to the remaining experts to reach a similar result, a stipulation to dismiss was entered, preserving all appellate rights [A1682]. Judgment was entered. This appeal follows.

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[1] Paginated references designated "A" are to the appellate appendix.

SUMMARY OF ARGUMENT

1. Exclusion of qualified and well-supported expert testimony about AMD's misconduct without analysis was an abuse of discretion.

2. Delaware's evidentiary law governed the admissibility of expert proofs. Because Dr. Frazier's uncontradicted opinions concerning causation were relevant, reliable, and rested on proper methodology satisfying Delaware law, they were improperly stricken.

3. The Superior Court's threshold ruling that Texas' substantive law governed this action was incorrect. AMD is a Delaware corporation, whose principal place of business is California. It operates substantially similar facilities worldwide. AMD's misconduct occurred in California and was implemented globally. Choice of law rules point to the application of Delaware or California law.

4. Even if Texas' substantive law applied to this action, and even if the authorities AMD cited about the admissibility of expert proofs constituted substantive Texas law, they would not bear on the issue of admissibility at a *Daubert* hearing. Furthermore, Dr. Frazier's uncontradicted opinions satisfied even AMD's extreme interpretation of Texas law, including referencing epidemiological studies showing a doubling of the risk, and exposures comparable to those at AMD. In ruling otherwise, the Superior Court misread and overlooked key portions of the record, substituted its own factually unsupported opinions for those of qualified and credible experts, and improperly denied Plaintiffs the right to present a fact question to a jury.

STATEMENT OF FACTS

1. Dr. Frazier's Opinions

Dr. Frazier opined, to a reasonable degree of certainty, that a cause and effect relationship existed between Jake and Paris' malformations, and their parents' exposures to specific chemicals at AMD [A740-A815; A1381-1389]. These chemicals all are reproductive toxicants with the capacity to cause Plaintiffs' birth defects [A632-639; A653; A656; A659]. Exposures were at times and levels capable of causing the malformations [A481-506; A509-550; A617-626], and were a substantial factor in causing them [A659-682]. Dr. Frazier carefully ruled out alternative explanations [A1314-1317; A774-777; A811-813].[2]

2. Credentials and Qualifications

As the Superior Court wrote, and AMD did not dispute,

> Dr. Frazier's credentials are impressive. She is an internist, board certified in occupational medicine. She also has a master's degree in public health, concentrating in epidemiology. Dr. Frazier has extensive experience studying epidemiology and occupational reproductive hazards . . . . In short, Dr. Frazier possesses the knowledge, skill, experience, training and education to assist the trier of fact to understand the evidence in this case. Her primary expertise includes the fields of internal medicine, occupational or industrial medicine, epidemiology, reproductive health and hazard assessment. Dr. Frazier is competent to interpret and explain the meaning of data, reports and studies in those fields[3] [2012 Op., p.12].

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[2] Dr. Frazier further opined that the manner in which AMD operated its workplace departed from good and accepted standards of workplace safety and industrial medicine, and foreseeably placed Wendolyn Tumlinson, Anthony Ontiveros and their prospective offspring at grave risk for reproductive harm including birth defects [A740-A815].

[3] The other experts' substantial qualifications were also unchallenged.

3. The Child Plaintiffs' Malformations

Jake was born on July 5, 1987. His multiple serious anomalies include an imperforate anus and abnormal connection between colon and bladder. He suffers from severe defects of the urinary system, including a hypoplastic right kidney and a neurogenic bladder. Malformations also affect his third, fourth, and fifth lumbar vertebrae, and spinal cord. Surgeries to construct a functioning anus and repairs to his urinary system proved unsuccessful. He is incontinent, subject to fecal impactions, and requires daily enemas. Jake is also incontinent of urine and voids through a catheter. Jake is likely infertile, and suffers from musculoskeletal pain as vertebral anomalies make his left shoulder higher than his right, and right leg shorter than his left [*See* A746-747].

Paris was born on August 12, 1994. Her grave cardiac anomalies include transposition artery stenosis, pulmonary artery occlusion, pulmonary atresia, large inlet and apical ventricularseptal defects, ventricular inversion and pericardial effusions. Extensive treatment has included four open-heart surgeries, resulting in post-operative stroke, semiparesis, and brain damage. Paris also was diagnosed with dextocardia and situs inversus, conditions in which locations of organs in her chest and abdomen are reversed [*See* A786-788].

4. The Parent Plaintiffs' Occupational Exposures at AMD

Wendolyn Tumlinson began work in Fab 11's photolithography section at AMD in spring 1986. Upon learning that she was pregnant in December 1986, she sought transfer to a non-chemical environment. AMD falsely assured her that her work created no risk, and continued her

there until late April 1987 [A1570; A883-886; A889-892]. Thus, the exposures below spanned the first 6 months of Jake's conception and gestation, the period of maximum fetal vulnerability [*Id.*; A582; A601-602; A762].

Anthony Ontiveros was an etch operator at AMD's Fab 14 facility in Austin, Texas from January 1992 to December 1995. As Paris was born in August 1994, Anthony's wrongful exposures occurred before, during, and after Paris' conception [A1574-1576 ¶¶70-79; A871-873; A869].

As described in the record, the parents' AMD employment involved chemical exposure via dermal absorption and inhalation. They directly handled chemicals at their work stations, and inhaled chemical vapors from adjacent workstations [*See* A484-485; A622; A653 ¶236; A688 ¶326; A852; A868-869; A1581-1587]. Spills and leaks increased exposures [A1494-1503; A887-888; A484-485; A624; A1581-1583].

Plaintiffs identified ten causation chemicals, which Dr. Frazier and her colleagues considered of principal interest to both children [A483-486].[4] Plaintiffs' experts also addressed the totality of exposures which the worker parents experienced [*See, e.g.*, A612-641].[5]

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[4] The chemicals are ethylene glycol monoethyl ether and its acetate; ethylene glycol monomethyl ether and its acetate; xylene; n-butyl acetate; arsine; isopropanol; methyl ethyl ketone; acetone; hexamethyl disilazine; and specific fluoride compounds (*e.g.*, freons and hydrofluoric acids) [A483-484].

[5] Throughout the proceedings, the Superior Court expressed reservations about allowing Plaintiffs to prove all of the exposures the parents experienced, based on its concern that that describing the array of chemicals present at AMD would unfairly prejudice the jurors and allow the Plaintiffs to "get millions of dollars in damages" [*E.g.*, A354-356; A377]. To allay its concern, Plaintiffs' experts identified ten specific causation chemicals of particular concern, [A483-A486], while explaining that a totality of the exposures analysis remained proper [A612-641].

Each causation chemicals was a reproductive toxin [A632; A653; A656; A659 *et seq.*]. This was documented through peer-reviewed literature including studies by Johns Hopkins University ("JHU") on behalf of IBM [A247-250; A896], and the University of California on behalf of the Semiconductor Industry Association ("SIA"), to which AMD belonged [A250-258; A930-952]. In these and other studies, reproductive toxins at AMD's facilities were identified, and workers' exposure levels evaluated [A627-642]. The parents' workplaces were substantially similar to the studied facilities [A640-641; A958-965; A1600-1604; A1323; 1366; A1368; A1530-1536]. In fact, the SIA Study included AMD's own facilities [A755]. There was basis to conclude that the exposures documented were applicable to this case [A1530-1536; A957-964].

Two exposure experts, James Stewart Ph.D. and Scott Reynolds M.S, P.E., quantified exposure in these cases, using different but equally accepted methodologies. [A1063-1094; A969-1035]. Plaintiffs' experts also analyzed actual monitoring data from the facilities to confirm, in yet another way, the exposure levels. [A690-693; A1063-1094; A969-995; A999-1035]. The exposures documented in these cases from multiple sources, utilizing multiple methodologies, were equal to or higher than levels shown to produce reproductive harm, and birth defects in particular [A1474-1477].

5. Methodologies

a. Weight-of-the-Evidence

Dr. Frazier and her colleagues utilized a weight-of-the-evidence methodology to evaluate causation. It marshals all relevant

information from all relevant disciplines (*e.g.*, clinical observations, case reports, epidemiological studies, animal studies, toxicological experiments, industrial hygiene and engineering studies, genetic testing and biochemical experiments, embryological information and medical diagnoses). Data is assessed for internal and external validity, *i.e.*, the quality of each study and its importance to the question posed. [A564-567].

Dr. Frazier and her colleagues assembled studies from numerous disciplines [A488-550]. These included epidemiological studies [A509-549]; animal studies [A488-502; A571]; experiments [A488-506]; government studies, investigations, and reports [A703-713; A1095-1154]; medical records [*see* A479-482]; exposure records [A876-881]; and industry records [*Id.*; A509-549; A1494-1509]. The Superior Court did not question Dr. Frazier's thoroughness in amassing materials.

b. Bradford-Hill

Epidemiologists use the Bradford-Hill factors to assess causation [A567-572].[6] By affidavit and at the hearing, Dr. Frazier explained how she evaluated evidence using each factor in reaching opinions [A1381-1389; A1538-1548; A1627-1628]. The Superior Court did not fault her use or application of Bradford-Hill.

c. Epidemiology

Dr. Frazier and her colleagues also presented evidence from leading epidemiological treatises respecting how that discipline evaluates causation. These treatises demonstrated how Plaintiffs'

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[6] *Milward v. Acuity Specialty Prods. Group, Inc.*, 639 F.3d 11, 17 (1st Cir. 2011); Federal Judicial Center Reference Manual on Scientific Evidence (3d Ed. 2001)("Reference Manual"), at 600.

experts treatment of a robust body of relevant literature was faithful to epidemiology and supported their opinions [A572-590; A509-549].

Dr. Frazier clarified the meaning of statistical measures (odds ratios, relative risks and confidence intervals) in epidemiological studies, describing their uses and abuses [A573-578].[7] As she explained, epidemiology does not require studies with odds ratios of 2 and 95% confidence intervals in order to infer causation [A576-578].

d. Differential Diagnosis/Differential Etiology

Dr. Frazier also employed differential diagnosis or etiology, a clinical approach. It allowed her to rule out alternative explanations while considering evidence showing chemical exposures to be the true cause of the Plaintiffs' malformations [A591-593; A1314-1317].

6. Medical and Scientific Evidence Supporting Causation

Dr. Frazier relied on a body of medical and scientific evidence in reaching her opinions. Most were peer-reviewed studies, government publications, or standard texts. None was generated for litigation.

Dr. Frazier and her colleagues assembled tables of peer-reviewed studies for the Court's reference. Mindful of AMD's claim that Texas requires studies with odds ratios or relative risks of 2.0 and

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[7] "Relative risk" measures the incidence rates of a disease or condition in exposed versus unexposed groups [A573-575]. "Odds ratio" is the odds of disease in the exposed population divided by the odds of disease in a control population. For relative risks and odds ratios, a value of "1" means that a study revealed no increased incidence of disease, and "2" shows a doubling of incidence [*Id.*]. "Statistical significance" concerns the likelihood that a study result might have occurred by chance, as opposed to an actual association [*Id.*]. A "confidence interval" indicates the stability of a study result. Thus, a 90% confidence interval would indicate a 9 in 10 likelihood that results were actual rather than chance. A 95% interval indicates a likelihood of nineteen out of twenty [A575].

confidence intervals at 95%, Plaintiffs' experts presented tables identifying such studies relevant to weight-of-the-evidence analysis [A507-549]. Many directly considered the semiconductor industry, and looked at a range of reproductive outcomes including birth defects [e.g., A1036-1039]. Others looked at comparable industries involving exposures to the same or similar chemicals, or exposures to specific chemicals present in Plaintiffs' worksites [e.g., A1041-1046; A677-678; A533-534 (Hooiveld, Cordier, and El Zein)]. Still others looked at related adverse outcomes (*e.g.*, miscarriage, infertility, and childhood cancers), which are well-established to be related to malformations [e.g., A512-517; A550]. Dr. Frazier explained why the studies, individually and collectively, "fit" these cases in terms of exposure and outcome. [*See, e.g.*, A1381-1392; A587-588; A1371-1372].

Dr. Frazier also considered peer-reviewed toxicological studies of the chemicals at issue. They consistently documented, in multiple species, the causation chemicals' capacity to produce birth defects [A488-506]. They evaluated effects of single doses of exposure [A488-491], exposure to multiple chemicals (as at AMD) [A492-493], and exposures producing Jake and Paris' injuries [A495-502].

Dr. Frazier addressed *in vivo* and *in vitro* studies supporting her conclusions [A488-503; A600-601]. She ruled out alternative explanations for the injuries [A1314-1317; A591-593; A774-777; A811-813]. She also discussed industry and government documents showing AMD's misconduct [A763-774; A806-811; A597-600; A1095-1154].[8]

[8] Space constraints make it impossible to convey the wealth and persuasive force of Dr. Frazier and her colleagues' proof.

7. Factual Errors in the Superior Court's Analysis

The opinion below repeatedly misstated or overlooked important record evidence. Examples of its serious errors include the following:

First, the Superior Court found that "Dr. Frazier did not analyze the exposure levels of each chemical." In fact, Dr. Frazier, Dr. Stewart, and Mr. Reynolds quantified the exposure levels that the Plaintiffs experienced, using alternative accepted methodologies and existing data [A966-1035; A1063-1094; A1474-1480]. These were meticulously compared and charted against the levels documented in studies on which she relied, and shown to be equal or higher, often by orders of magnitude [A1474-1480; A1329]. Further, even when referencing studies which did not quantify exposures, Dr. Frazier explained how epidemiological methodology, looking *inter alia* to other published data respecting exposure levels in the studied industry, permitted comparison between Plaintiffs' exposures and those in literature [A1330-1331; 1632-1633; 1372].

Second, the opinion discounted the Lin study. Dr. Lin found a more than fourfold increase in cardiac malformations in male semiconductor workers' offspring [A1036-1039]. Mr. Ontiveros was a semiconductor worker. Paris has cardiac malformations. By any reasonable measure, Lin is a perfect "fit" with the Ontiveros case.

Highlighting part of this evidence runs the risk of diminishing the full impact of the entire corpus. There is no substitute for a review of the Joint Affidavit [A470 *et seq.*], Dr. Frazier's Individual Affidavit [A1155 *et seq.*], and her testimony [A1287-1473], particularly the portions summarizing her opinion analysis [A1381-1389]. Plaintiffs respectfully ask the Court to focus on these items and Plaintiffs' Proposed Findings of Fact [A1549 *et seq.*] for a fuller appreciation of the proofs.

Third, the Superior Court found that the Lin study did not address birth defects. In fact, Lin reviewed birth defects so severe that the children died [A1036; A1365]. Thus, by excluding live children from the study, Lin was *understating* the number of birth defects which occurred in the studied population [A1366].

Fourth, it found that Lin "lacked adequate exposure measurements, and involved a Taiwanese workplace–which may or may not mirror the AMD workplace." This ignored an important affidavit Plaintiffs provided from James Stewart, Ph.D., who was a technical consultant to the Lin study. Dr. Stewart confirmed that the plants which Lin studied (making chips for American manufacturers with precise specifications), were substantially similar to AMD's plants [A1530-1536].[9]

Fifth, the Superior Court found that Sung's study did not report odds ratios on birth defects, and lacked exposure measurements. [2012 Op., p.19.] To the contrary, Sung reported a *fivefold* increase in cardiac anomalies in workers offspring. [A1041; A677]. Further, Sung's usage of job title as a surrogate for exposure level is a widespread and well-accepted method in epidemiology [A1330-1331].

Sixth, it suggested that Plaintiffs' experts relied only on research concerning "other fields or other places." [2012 Op., p1]. This overlooked *inter alia* the studies of Lin, Gray, Pastides, Schenker, Beaumont, Correa, Swan, and Eskenazi, involving semiconductor workers [A509-517]. Indeed, AMD's own facilities were

[9] Dr. Frazier also explained that, where as was the case in Lin, a peer-reviewed epidemiology publication addresses a well-studied industry, it would be disclosed if exposure levels in the studied facilities differed from the norm [A1368].

included in the SIA Study [A755].

Seventh, the Superior Court criticized Dr. Frazier for not "confirm[ing]" her opinion ruling out maternal obesity as a cause of Jake's injuries. One can only "confirm" that obesity did not cause Jake's injuries by showing a lack of evidence to that effect. This Dr. Frazier did. She carefully analyzed studies on weight and birth defects, citing *inter alia* a comprehensive meta-analysis in explaining why Wendolyn Tumlinson's weight, which did not include gestational diabetes, did not cause Jake's malformations. Dr. Frazier identified key shortcomings in numerous studies respecting maternal weight, including failure to control for diabetes, and lack of proper height and weight measurements [A774-777; A1314-1317]. Taking these factors into account, the meta-analysis did not support a causal relationship between maternal weight and Jake's birth defects [Id.]. Moreover, the Superior Court overlooked Dr. Frazier's testimony that even if obesity had contributed to Jake's injuries, it would be as part of a multi-factorial etiology whereby AMD exposures exacerbated the harm [A344-345; A1316].

Eighth, it ascribed to Dr. Frazier the view that "other unidentified chemicals that contributed to the children's birth defects." In fact, Dr. Frazier identified 10 chemicals, explaining that each was a substantial factor in causing the birth defects, and also referenced the totality of exposures as a cause [A483-486; A612-641]. She did not say that other chemicals individually caused these defects. The cited testimony simply indicates that other chemicals were likely present whose identities were not specifically known.

[A1344-1345; A1351-1352].

Ninth, the Superior Court discounted studies of "chemicals in the same family" as those at AMD, finding that "there is nothing quantifying the difference in toxicity levels between the studied chemical and the related chemical." This ignored the many studies Dr. Frazier cited involving the chemicals at AMD [A488-517; A1388]. It also was entirely proper under the Bradford-Hill criteria to reference studies showing the capacity of related chemicals to cause harm [*See, e.g.*, A567-572; A1158-1160]. Furthermore, contrary to the Court's finding, the record showed that the ethylene glycol ethers at AMD were among the most potent members of the glycol ether chemical family. [A228-229; A1054; A1403; A1460; A1526-1529; A1568-1587].

Tenth, the decision below made reference to "federally approved clean rooms." This may reflect a view that clean rooms were government inspected or endorsed. The record does not support that claim, nor do clean room standards relate to overall safety [A797-799].[10]

Eleventh, the Superior Court incompletely described the exposures at issue. Its opinion referenced Mr. Ontiveros' exposures to sulfuric acid, hydrogen peroxide, hydrofluoric acid, ammonium fluoride and isopropyl alcohol. His exposures to well-documented teratogenic chemicals including photoresist, ethylene glycol, acetone, n-Butyl acetate, and 2-methoxy ethanol were unaddressed [A615-620].

Twelfth, the opinion overlooked proof about how the totality of exposures was studied in peer-reviewed literature, and matched to the exposures the parents experienced [A612-659]. The group of chemicals

[10] Clean rooms were also incorrectly called "cold rooms" (2012 Op., 9).

commonly used in semiconductor manufacturing including at AMD have been evaluated and measured in many studies [A627-645]. Peer-reviewed industry-funded studies found adverse reproductive outcomes with odds ratios in over 2.0 and with good statistical power [A896-952].

Thirteenth, the Superior Court dismissed proof linking miscarriages in the semiconductor studies and birth defects [A1234-1269].[11] As Drs. Frazier and Kramer explained, a wealth of human and animal data establish that miscarriages are an *a fortiori* surrogate for birth defects [A244; A583; A589-590; A606; A1355; A1566-1567; A1617; A1612-1613]. Ample literature illustrated this well-accepted principle. [A1234-1269].

Fourteenth, the Superior Court criticized Dr. Frazier's testimony about the dose-response relationship between spontaneous abortion and malformations as "untested and vague." Studies and well-recognized texts confirmed that this proposition has been tested and accepted [A1234-1269]. Dr. Frazier explained why this is so, without contradiction [A1353-1357; A570; A606; A656; A660-661].

Fifteenth, the opinion overlooked that Dr. Frazier isolated specific chemicals to which the Plaintiffs were exposed, each of which was sufficient to proximately cause these birth defects [A509-532; A643-656]. To illustrate, ethylene glycol ether exposures alone were sufficient to cause Plaintiffs' malformations [A1325-1327; A1374-

[11] Nor was there an accurate discussion of the manner in which those studies dealt with birth defects. Although they assert that birth defects were not the object of their study, as Dr. Frazier and her colleagues pointed out, the actual data in IBM's study revealed elevated levels of birth defects with good statistical power and odds ratios exceeding 2.0 [A606; A629-632; A680-681; A683-684].

1376]. Having earlier criticized Plaintiffs for perceived imprecision in identifying the chemicals present at AMD, the Court itself did not address the chemical-specific proofs in its opinion.

The foregoing paragraphs merely identify the most serious errors; space constraints prevent a complete itemization. Each error was material and warranted reversal. Taken together, they reflect a failure to engage with a robust record supporting credible and uncontroverted opinions.

8. AMD's Misconduct

Dr. Frazier and her colleagues opined that:

> By the mid-1980s, professional standards pertaining to protecting worker health existed in occupational medicine and occupational health nursing, and were not followed by AMD with respect to Mrs. Tumlinson;
> [W]hen it came to pregnant women such as Mrs. Tumlinson, it was AMD's policy to provide lesser care by deferring decision-making to the employee's personal physician, rather than using the more extensive resources available at AMD. A lesser standard of occupational safety and health for pregnant workers is not justified and was not consistent with standards of occupational health practice in the 1980s. There was no justification for this in the occupational medicine literature, nor in professional or regulatory standards of the time.
>
> [A]t the time of Paris Ontiveros's conception, a great deal was known about dermal exposure to hazardous chemicals, and about paternal chemical exposures causing problems with fertility and adverse effects on the children they conceived. AMD health and safety personnel should have been very familiar with this literature;
>
> AMD industrial hygiene, health and safety professionals and toxicologist should have read and acted upon the warnings issued by government and the very large number of articles in the toxicology literature at that time showing that chemicals in the Fab room were male and female

> reproductive and developmental toxicants . . . [including] glove and dermal exposure issues, as well as the effect of exposure to chemical mixtures discussed above.

[A745; A766; A806; A811]. These opinions were extensively supported. Dr. Frazier's background qualifies her to so opine [A556-560].

9. Factors Relating to Choice of Law

AMD is a Delaware corporation with principal places of business in California, and facilities worldwide. Its negligent health, surveillance, and hazard communication policies were conceived in California, and caused harm worldwide [A182]. California Vice Presidents inspected Texas operations [A194]. The Committee which removed reproductively hazardous glycol ethers from AMD in 1993, and failed to do so earlier, also consisted principally of California executives [A335; A338-342].

ARGUMENT

I. THE SUPERIOR COURT IMPROPERLY EXCLUDED DR. FRAZIER'S OPINIONS CONCERNING AMD'S MISCONDUCT WITHOUT ANALYSIS

a. Question Presented

Was preclusion of qualified, credible, and uncontroverted expert opinions respecting AMD's misconduct without analysis improper?

b. Scope of Review

Rulings on the admissibility of expert testimony are generally reviewed for abuse of discretion.[12] However, failure to make findings or supply reasons for a ruling may itself constitute an abuse.[13]

c. Argument

Dr. Frazier opined on misconduct and causation. As to misconduct, she opined that AMD knew or should have known of the reproductive hazards posed by the chemicals at issue, and failed to provide safeguards to protect workers and their future offspring from such exposures [A748-774, A788-811]. Plaintiffs also proffered a "state-of-the-art" report of occupational health physician, Robert Harrison, M.D. Dr. Harrison documented the semiconductor industry's and scientific community's knowledge concerning the reproductive toxicity of the chemicals with which the Plaintiffs' parents worked [A816-866].

While AMD sought to exclude Dr. Frazier's opinions that it breached a duty, it never challenged her qualifications to so opine, which are unimpeachable [A781-785; A1202]. Nor did AMD identify any colorable basis for questioning the reliability of her opinions. Rather, AMD's brief merely included an unsupported argument suggesting

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[12] *New Haverford P'ship v. Stroot*, 772 A.2d 792, 798 (Del. 2001).
[13] *Holden v. State*, 23 A.3d 843, 846-847 & n.8-10 (Del. 2011).

that it could not have breached a duty because its workplace's hazards were somehow unforeseeable [A405 n.5; A1202].

That is flatly incorrect. Drs. Frazier's and Harrison's opinions concerning foreseeability were amply supported by their extensive knowledge of occupational medicine, in which both physicians are board certified, and a wealth of evidence. It included, but was not limited to, federal and state government warnings about the hazards posed by semiconductor manufacturing chemicals, warnings from chemical suppliers, internal documents from IBM, deposition testimony, and epidemiological studies conducted by the semiconductor industry itself. [A763-774; A806-808; A816-866; A1095-1154; A1510-1525]. Here, as elsewhere, AMD proffered no expert to challenge this showing. Nor did AMD identify any problems with the methodology Dr. Frazier and Dr. Harrison employed in reaching their opinions concerning foreseeability or misconduct.

AMD provided no reasoned basis for excluding Dr. Frazier's opinions as to misconduct. Nor did the Superior Court make any findings or supply any reasons before striking her testimony in its entirety. Its decision to do so, without analysis or explanation, constituted an abuse of discretion.[14]

[14] *Holden*, 23 A.3d at 846 & n.9 (citations omitted).

II. DR. FRAZIER'S CAUSATION OPINIONS SATISFIED *DAUBERT*, AND WERE THEREFORE ADMISSIBLE

a. Question Presented

Where Dr. Frazier's impressive qualifications were undisputed, and her testimony relevant, reliable, and unchallenged by any defense expert, were her opinions respecting causation wrongly excluded?

b. Scope of Review

A decision properly applying Delaware's jurisprudence to expert testimony ordinarily would be reviewed for abuse of discretion.[15] However, because the Superior Court never reached the proper question of whether Dr. Frazier's opinions satisfied *Daubert*, and instead precluded them by misapplying Texas law, *de novo* review is required.[16]

c. Argument

By stipulation and order,[17] Delaware law governed admissibility of expert proofs. Delaware has adopted *Daubert v. Merrell Dow Pharms*, which holds that expert testimony must be relevant and reliable to be admissible.[18] The "flexible" inquiry it envisions focuses "solely on principles and methodology, not on the conclusions they generate."[19]

Recognizing the "liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to opinion

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[15] *Rodriguez v. State*, 30 A.3d 764, 769 (Del. 2011).
[16] *See Holden*, 23 A.3d at 846 ("To the extent the claim of error implicates questions of law … the standard of review is *de novo*.")
[17] A142-143; Opinion Granting Motion to Exclude Frazier ("2012 Op.")("Evidentiary matters … including the admissibility of expert opinions, are governed by the Delaware Rules of Evidence"); Opinion Granting Motion to Apply Texas Law ("2010 Op.") (same).
[18] *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 589 (1993); *Rodriguez*, 30 A.3d at 769.
[19] *Daubert*, 509 U.S. at 594-95.

testimony," *Daubert* rejected rigid acceptance criteria.[20] In evaluating admissibility, a court may consider whether an expert's theory or technique (1) can be or has been tested; (2) has been subjected to peer-review and publication; (3) has a high known or potential rate of error and whether there are standards controlling its operation; and (4) enjoys general acceptance within a relevant scientific community.[21] This State's courts also ask whether (a) the expert is qualified by knowledge, skill, experience, training or education; (b) the evidence is relevant and reliable; (c) her opinion is based upon information reasonably relied upon by experts in the field; (d) the testimony will assist the trier of fact to understand the evidence or determine a fact in issue; and (e) testimony will create unfair prejudice, confuse, or mislead the jury.[22]

Notably, although "[e]pidemiological studies have been well-received by courts," there is no "requirement that an expert opinion be based on epidemiology in order to be admissible."[23] *In vitro* and *in vivo* studies also are employed by physicians, scientists, and government agencies, and may support causation.[24] Moreover, "vigorous cross-examination, presentation of contrary evidence and careful instruction on the burden of proof are the traditional and appropriate

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[20] *Daubert*, 509 U.S. at 588 (quotations and citations omitted).
[21] *Id.* at 590-94.
[22] *Cunningham v. McDonald*, 689 A.2d 1190, 1193 (Del. 1997).
[23] Reference Manual on Scientific Evidence (3d Ed.), at 551 n.2 (citations omitted); *See GMC v. Grenier*, 981 A.2d 531, 539 (Del. 2009); *Milward*, 639 F.3d at 24; *Ambrosini v. Labarraque*, 101 F.3d 129, 138 (D.C. Cir. 1996).
[24] *See, e.g., In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 732 (N.D. Ohio 2011); *Ruff v. Ensign-Bickford Indus., Inc.*, 168 F. Supp. 2d 1271, 1281 (D. Utah 2001); *see also Cagle v. Cooper Cos.*, 318 F. Supp. 2d 879, 909-11 (C.D. Cal. 2004); A1335.

means of attacking shaky but admissible evidence."[25]

Had the Court applied this law to the case, Dr. Frazier's opinions clearly would have been admitted. She opined on misconduct and causation, both of which were relevant to Plaintiffs' claims.[26] Her unchallenged qualifications were praised below. The differential diagnosis or etiology method she used to assess specific causation is well-accepted in medicine and law.[27] The same is true for the weight-of-the-evidence methodology she employed in evaluating general causation, following the Bradford-Hill guidelines [A1381-1389].[28] The studies on which Dr. Frazier relied were tested, peer-reviewed, not generated for litigation, and had error rates which may be examined.

Nor was there any basis for questioning her "intellectual rigor" in applying these techniques.[29] As discussed, Dr. Frazier and her colleagues evaluated all relevant information from pertinent disciplines including animal studies, experiments, government reports, medical records, and industry records. Significantly, the latter included acknowledgement by scientists hired by the industry that the causation chemicals had adverse reproductive and/or developmental effects in humans, animals, or both [A896-953]. Indeed, the rich toxicological literature included highly specific showings that

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[25] *Rodriguez*, 30 A.3d at 770 (quoting *Daubert* 509 U.S. at 595-96).
[26] Evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Del. R. Evid. 401.
[27] *Granfield v. CSX Transp., Inc.*, 597 F.3d 474, 486 (1st Cir. 2010); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262-66 (4th Cir. 1999).
[28] *Milward*, 639 F.3d at 17-20, 23; *see also Grenier v. GMC*, 2009 Del. Super. LEXIS 548, *30-32 (Del. Super. Ct. Feb. 4, 2009) (Bradford-Hill constitutes "sound methodology"), *aff'd* 981 A.2d 531 (Del. 2009).
[29] *Kumho Tire v. Carmichael*, 526 U.S. 137, 152 (1999).

exposing animals to glycol ethers on certain gestational days produced Jake's anomalies. [*E.g.*, A499-502; A1255-65; A1278-86; A1385].

Moreover, while such studies are not required, Dr. Frazier evaluated myriad epidemiological studies corroborating toxicological evidence that the clean room chemicals are capable of causing Jake's and Paris birth defects [A495-549]. For instance, one peer-reviewed study found that the offspring of male semiconductor workers had a more than four-fold increase in cardiac anomalies, Paris' very injury [A1036-1040]. Another reported a fivefold increase in cardiac anomalies in offspring of male electronics workers, a field which encompasses semiconductor manufacturing and is classified with it because of their similarities [A1041-1046; A1371-1373; A1381]. As explained below, the studies likely understated those risks [A1365].

Further supporting Dr. Frazier's opinions was Dr. Cordier's peer-reviewed research showing that the offspring of women exposed to glycol ethers have increased rates of multiple anomalies like Jake, and anomalies from which Jake suffers [*See* A1047-1062]. Corroborating those findings and dozens of animal studies [A488-506] were large peer-reviewed epidemiological studies conducted by the semiconductor industry, one of which evaluated AMD's facilities. With striking consistency, they found statistically significant associations between the parents' work and spontaneous abortion [A511-516; A893-952]. This strongly supported causation because it is a well-known principle in toxicology that larger doses of toxins produce miscarriages while lower doses produce birth defects, reaffirmed in numerous publications provided to the Superior Court [A1386-1387; A1355-1357; A494; A1234-

1269; A244]. Finally, Dr. Frazier performed differential etiology, carefully ruling out alternative causes posed by AMD [A1313-1317].

AMD could not seriously dispute the propriety of these methodologies or the intellectual rigor of the analysis. Consequently, it tried to cast doubt on Dr. Frazier's conclusions, by arguing that no epidemiological, *in vitro,* or *in vivo* study, industry document, or government publication was relevant unless it independently satisfied Texas' supposed standards for admissibility. [A383-426].

The legal impropriety of AMD's invocation and interpretation of Texas law is addressed *infra*, at Point III. For present purposes, it is important to underscore that the Superior Court never found Dr. Frazier's testimony inadmissible under *Daubert*. Nor would the record support such a finding. In that regard, AMD chose to submit no expert proof supporting its critique. No physician or scientist challenged Dr. Frazier's methodology, or even her conclusions.

In a case as serious and complex as this one, this unorthodox approach offered no basis for preclusion.[30] Plainly, AMD's counsel were not scientists or physicians competent to challenge Dr. Frazier's testimony that the studies at issue supported causation. Nor could the Court simply discount Dr. Frazier's testimony about the strong support complex scientific studies offered for her conclusions without

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[30] In that regard, parties challenging expert testimony routinely proffer experts supporting their positions. *E.g., Daubert,* 509 U.S. at 582; *Joiner v. GE,* 78 F.3d 524, 534 (11th Cir. 1996); *In re Asbestos Litig.,* 911 A.2d 1176, 1194 (Del. Super. Ct. 2006); *L.B. Corp. v. Schweitzer-Mauduit Int'l, Inc.,* 121 F. Supp. 2d 147, 156 (D. Mass. 2000). Indeed, AMD's counsel implicitly acknowledged this below, conceding that "if the Court had not ruled that [Texas law] applied, [AMD] would not be here without our experts" [A1296].

guidance from a qualified expert. "[J]udges are not scientists and do not have the scientific training that can facilitate the making of such decisions."[31] As the Superior Court observed, AMD's strategy created a one-sided record, consisting of Dr. Frazier's explanation of the significance of studies and the propriety of her methodology, unchallenged by any expert. [*See* A1470]. Faced with credible expert testimony explaining why scientific studies fit, AMD's counsel's espousing a contrary position was no basis for exclusion.

In any event, assuming *arguendo* their competence to advance such criticisms, AMD's counsel at most identified possible areas for cross-examination rather than a basis for removing this question from a fact-finder. In essence, AMD asked the Court to reject every authority Dr. Frazier cited, claiming that a study is relevant only if it exposed: a) human beings b) of childbearing age c) to precisely quantified reproductively hazardous substances, d) identical in every respect to those at AMD, e) producing exactly the injuries Paris and Jake have [A383-426]. Such a rule would bar any child injured by toxic exposures from recovery, because it would call for human experimentation abhorrent in civilized society. Such studies would also, of necessity, imperil an enormous segment of the populace, given the low frequency of many birth defects. Moreover, such a requirement is inconsistent with the scientific method, as Dr. Frazier explained while describing why the studies at issue fit and constituted strong evidence of causation. [*See* A1155; A1371-1372; 1388].

Furthermore, AMD's "atomistic" approach of considering each study

[31] *See GE v. Joiner*, 522 U.S. 136, 148 (1997)(Breyer, J. concurring).

in isolation, and deeming it irrelevant if it did not demonstrate causation by itself, is inconsistent with *Daubert*.[32] Nor does this Court require experts to establish the foundation for an expert's causation opinion "with the precision of a laboratory experiment" or "eliminate other possible causes of plaintiffs' health problems," as AMD claimed.[33] In short, the criticisms AMD's counsel launched -- unendorsed by a single competent expert – at most went to the weight rather than the admissibility of Dr. Frazier's opinions.[34]

Finally, while even AMD did not seek exclusion on this basis, the Court below expressed an unfounded concern that Dr. Frazier's opinions might confuse jurors or create unfair prejudice. It reasoned that "epidemiology" poses a "the risk of a verdict based on an incorrect

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[32] *See, e.g., Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 632 (8th Cir. 2012)(while studies were "not perfect, they provide[d] useful information that, along with [another] study, provide[d] an adequate foundation" for expert opinion); *Milward*, 639 F.3d at 22-23, 26 (trial court abused discretion by "derived from a mistake in its understanding of the weight of the evidence methodology employed ... [by] treat[ing] the separate evidentiary components of Dr. Smith's analysis atomistically, as though his ultimate opinion was independently supported by each.... The hallmark of the weight of the evidence approach is reasoning to the best explanation for all of the available evidence.")(citations omitted); *Grenier*, 2009 Del. Super. LEXIS 548, at *33-34 (allowing expert though "none of the epidemiological studies 'demonstrated' a positive association between exposure to friction products and disease").

[33] *New Haverford P'ship*, 772 A.2d at 799-800. *See also Grenier*, 2009 Del. Super. LEXIS 548, at *44 (plaintiff not required to disprove defendant's hypothesis at *Daubert* hearing).

[34] *Id. See also Ambrosini*, 101 F.3d at 141 ("By attempting to evaluate the credibility of opposing experts and the persuasiveness of competing scientific studies, the district court conflated the questions of admissibility of expert testimony and the weight appropriately to be accorded such testimony by a fact finder."); *L.B. Corp.*, 121 F. Supp. 2d at 155 ("It is not the function of the court to determine whether the plaintiff's expert did everything that an expert could do ... or whether every piece of information he relied upon was indisputably true and accurate.").

appeal to authority," quoting an excerpt from the hearing respecting ethylene glycol ethers. [2012 Op., 11-12]. The testimony merely explained that two related chemicals can metabolize to the same toxin, producing the same harmful effects, a proposition which is not unduly complicated or controversial, and was explained in a straightforward manner. Furthermore, if it found this testimony misleading, AMD was free to cross-examine Dr. Frazier at trial or offer contrary proofs.

Moreover, insofar as the Court was concerned that the causation chemicals sounded technical or sinister, that is hardly Jake or Paris' fault. AMD chose to expose their parents to substances it knew to be reproductive toxins [A816-866]. The chemicals' identities are well documented, and the studies supporting causation were discussed in a factual, even-handed fashion. *In limine* instructions could have cured any conceivable prejudice. *Daubert* does not support excluding Plaintiffs' experts simply because they discussed chemical names, epidemiology, or biology. Courts routinely permit qualified experts employing proper methodologies like Dr. Frazier to testify.[35] Assisting jurors in understanding technical subjects is just what D.R.E. 702 envisions. Accordingly, "[s]o long as an expert's scientific testimony rests upon ''good grounds,' based on what is known,'' it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities."[36]

In sum, Dr. Frazier's relevant and reliable testimony satisfied *Daubert*, and was improperly excluded.

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[35] *See, e.g., Kuhn*, 686 F.3d at 621; *United States v. Barnes*, 481 Fed. Appx. 505, 514 (11th Cir. 2012).
[36] *Milward*, 639 F.3d at 15 (*quoting Daubert*, 509 U.S. at 590, 596).

III. THE SUPERIOR COURT ERRED BOTH IN APPLYING TEXAS LAW TO *DAUBERT* PROCEEDINGS, AND IN THE MANNER IN WHICH IT APPLIED THAT LAW

a. Question Presented

Were applying Texas law to *Daubert* proceedings, and then finding that Dr. Frazier's opinions failed to satisfy that law, incorrect?

b. Scope of Review

The choice of law ruling is subject to *de novo* review.[37] As the ruling that *Merrell Dow Pharmaceuticals, Inc. v. Havner*[38] controlled *Daubert* proceedings was legal, it too must be reviewed *de novo*.[39]

c. Argument

As discussed above, the Superior Court never reached the true question of whether Dr. Frazier's opinions satisfied *Daubert*. Instead, it excluded them by: a) holding that Texas law governed this action, b) deeming *dicta* in *Havner* on the admissibility of scientific testimony substantive Texas law, c) applying *Havner* instead of *Daubert* at a *Daubert* hearing, and d) holding that Dr. Frazier's opinions did not satisfy Texas law. Plaintiffs respectfully disagree with those rulings. Importantly, however, error on even one of them would warrant reversal, as each step was critical to reaching the incorrect outcome.

1. Substantive Texas Law Did Not Govern this Action.

Before the *Daubert* hearing, AMD moved to apply Texas Law to Issues of Liability and Damages [A147-174]. The Superior Court agreed, reasoning that Texas was the place of injury, and had the most

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[37] *Cavalier Oil Corp. v. Harnett*, 564 A.2d 1137, 1141 (Del. 1989).
[38] 953 S.W.2d 706 (Tex. 1997).
[39] *See Holden*, 23 A.3d at 846 ("To the extent the claim of error implicates questions of law … the standard of review is *de novo*.").

"significant relationship" to the action [2010 Op., 8-9].[40]

That was incorrect. Delaware has abandoned the rigid *lex loci* rule, in favor of the most significant relationship test,[41] evaluating factors in Restatement (Second) Conflicts of Law §6[42] and §145.[43]

Those factors did not support the Superior Court's ruling. As Plaintiffs explained [A175-216], AMD executives based in California formulated the negligent policies which placed the Plaintiffs, and the offspring of thousands of other AMD employees, at risk. To illustrate:

AMD characterizes itself as "a global company [with] corporate offices, sales resources, and research & development facilities around the world with headquarters in Sunnyvale, California."[44]

AMD's Environmental Health and Safety ("EHS") policy statement proclaimed that "AMD's commitment to EHS starts at the top" and was signed by its California-based CEO [A349-350; A352].

AMD's deficient policies on hazard communication, health and safety, engineering, and industrial hygiene were all promulgated in

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[40] Notably the Court so ruled despite AMD's failure to identify a conflict of law bearing on the issues before it. This too was error.

[41] *Travelers Indem. Co. v. Lake*, 594 A.2d 38, 43-47 (Del. 1991).

[42] Restatement Section Six considerations are: (a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and relative interests of those states in determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of result, and (g) ease in determination and application of the law to be applied.

[43] Restatement Section 145 lists the following contacts to consider when applying Section Six: (a) place where the injury occurred, (b) place where the conduct causing the injury occurred, (c) domicil, residence, nationality, place of incorporation and place of business of the parties, and (d) where the relationship, if any, between the parties is centered.

[44] http://www.amd.com/us/aboutamd/contact-us/pages/locations.aspx (last visited February 6, 2013).

California [A325-329; A338; A342-345; A348; A350].

California AMD executives inspected Texas facilities [A346-347].

AMD's submicron development center, in California, made process changes implemented throughout AMD's operations [A335; A338-342].

AMD's decision to remove glycol ethers from facilities because of "negative reproductive outcomes" and "birth defects associated" with them in the mid-1990's - and its decision *not* to do so earlier -- was made by EHS executives principally based in California [*Id.*].

Industry members including AMD used standard practices removing meaningful distinctions between their semiconductor manufacturing facilities worldwide [*See* A323-324; A330-332; A842-844; A958-965].

Similar design, operation, chemicals, and equipment allowed University of California researchers to study clean rooms operated by companies nationwide to assess reproductive hazards [*Id.*; A245-258].

These studies showed remarkably consistent rates of reproductive harm among facilities run by many companies, including AMD [A245-258].

In short, the misconduct producing Plaintiffs' injuries emanated from high-level decisions made in California, not local acts of neglect. That the injuries occurred in Texas were coincidental, as the very same hazards plagued AMD's global operations. Applying Texas law needlessly burdened the Court below, particularly given the decision AMD invoked, whose rambling *dicta* have perplexed courts.[45] Nor did

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[45] *See e.g., Lofton v. McNeil Consumer & Specialty Pharms.*, 682 F. Supp.2d 662, 668-669 (N.D.Tx. 2010)(citing federal cases interpreting *Havner* in different ways); *Bartley v. Euclid, Inc.*, 158 F.3d 261, 273 & n.9 (5th Cir. 1998) (expressing uncertainty about whether *Havner* is substantive or procedural; finding that sufficient evidence supported plaintiff's verdict regardless).

Texas have an interest in applying its law if doing so would shield a California-based corporation from liability in Delaware. Rather, it has an interest in seeing its residents recover, to ease the State's health care costs.[46] AMD's invocation of Texas law lacked merit.

2. *Havner* Does Not Supplant *Daubert* at a *Daubert* Hearing

Assuming *arguendo* that substantive Texas law governed this action, applying it to a *Daubert* hearing was error. First, the parties stipulated that *Daubert* governed admissibility of expert proofs. That agreement was memorialized, so-ordered, and reaffirmed.[47] Plaintiffs engaged in extensive discovery in reliance thereon. AMD offered no reason for departing from that agreed-upon, court-ordered approach.

Second, applying *Havner* at *Daubert* hearings was incorrect because its guidelines on admissibility of expert proofs are procedural. By way of background, Texas views *Daubert* as authoritative respecting admissibility of causation proof.[48] However, *Havner* departed from mainstream *Daubert* jurisprudence by expressing preferences for epidemiological studies with odds ratios of 2.0, with exposures substantially similar to those of the plaintiff.[49] Such a requirement has been widely rejected as unsound, including by this Court.[50] Indeed,

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[46] Nor could AMD plausibly assert that it reasonably relied on *Havner* in its mistreatment of the parents, since that decision post-dated the child Plaintiffs' births by several years.

[47] A142-143; 2012 Op. ("Evidentiary matters … including the admissibility of expert opinions, are governed by the Delaware Rules of Evidence"); 2010 Op., p9-10 (same).

[48] *E.I. du Pont de Nemours & Co. v. Robinson,* 923 S.W.2d 549, 556 (Tex. 1995).

[49] *Havner,* 953 S.W.2d at 718.

[50] *GMC,* 981 A.2d at 539 ("an expert opinion [need not] be based on epidemiology in order to be admissible."). *See also, e.g., Milward,* 639 F.3d at 24; *In re Hanford Nuclear Reservation Litig. V. E.I.*

even Texas denies that such studies are a "litmus test."[51]

With that in mind, the portions of *Havner* cited by AMD address a classic procedural question: what standards expert testimony on causation must meet to be admitted at trial. The "local law of the forum determines the admissibility of evidence[.]"[52] Because the admissibility of expert proofs is an evidentiary question, concerned with establishing fair, accurate, and efficient dispute resolutions,"[53] it is controlled by the law of Delaware.[54] Since Delaware has adopted *Daubert* as the proper procedure for determining which expert proofs are admissible, the Superior Court should have applied *Daubert* to admissibility questions. Importantly, that is the approach typically taken by federal courts in diversity actions invoking Texas law.[55]

DuPont, 292 F.3d 1124, 1137 (9th Cir. 2002); *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062, 1079 (D. Kan. 2002); Reference Manual on Scientific Evidence, (3d ed.), at 611, n.186. ("While strength of association is a guideline for drawing an inference of causation from an association, … there is no specified threshold required.").

[51] *Havner*, 953 S.W.2d at 718.

[52] Restatement (Second) Conflict of Laws § 138 (1971).

[53] Rules which aim to achieve "fair, accurate, and efficient resolutions of disputes" are procedural. Meanwhile, if its "primary objective is directed to influencing conduct through legal incentives," a rule is substantive." *Sims v. Great Am. Life Ins. Co.*, 469 F.3d 870, 883 (10th Cir. 2006).

[54] *Ballard v. Keen Transp., Inc.*, 2011 U.S. Dist. LEXIS 10341, *1-2 (S.D. Ga. Feb. 3, 2011)(citation omitted).

[55] *See, e.g., Wells v. SmithKline Beecham Corp.*, 2009 U.S. Dist. LEXIS 21251, *22 (W.D.Tx. Feb. 18, 2009)("[t]he admissibility of evidence is a procedural issue governed by federal law...."), *aff'd*, 601 F.3d 375 (5th Cir. 2010); *Lofton*, 682 F. Supp.2d at 669 ("*Havner* does not control a federal court's determination of admissibility pursuant to Rule 702 and *Daubert*"); *Taylor v. Bristol Myers Squibb Co.*, 2004 U.S. Dist. LEXIS 30805, *3 (N.D.Tx. Sept. 15, 2004)(*Havner* does not "control the admissibility of expert testimony or scientific evidence in a federal court" in diversity); *id.* at *6 (noting "that the MDL court established to handle federal phenylpropanolamine ('PPA') cases has already determined that Plaintiffs' expert testimony and scientific evidence are admissible under *Daubert* standards). *See also*

Furthermore, even if *Havner* constituted substantive Texas law, it would at most relate to the sufficiency of the evidence at a summary judgment stage.[56] In contrast, *Daubert* motions are concerned with the threshold issue of whether expert opinions are admissible at trial.

The Superior Court overlooked the important distinction between admissibility and sufficiency. AMD could have filed a summary judgment motion challenging the sufficiency of the evidence. It did not. That strategic choice was doubtless driven by a desire to avoid the burden of proof associated with moving for summary judgment. Further, AMD recognized that in a summary judgment motion, the entire corpus of evidence would be reviewed in the light most favorable to Plaintiffs, drawing all reasonable inferences in their favor.[57] Yet, AMD's desires notwithstanding, it was not free to make a summary judgment application cloaked as a *Daubert* motion, and thereby tacitly abandon its burden of proof.[58] Since AMD's sole challenge was to the admissibility of Dr. Frazier's testimony, her opinions had to be evaluated under *Daubert*. As demonstrated *supra*, at Point II, had those standards been applied, her testimony would not have been excluded.

In addition to being erroneous, the application of *Havner* to

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Black v. Food Lion, Inc., 171 F.3d 308, 314 (5th Cir. 1999) (applying *Daubert* to admissibility question).

[56] *See Lofton*, 682 F. Supp.2d at 669 (rejecting claim that *Havner* bears on the admissibility of expert testimony because that argument "conflate[d] the standards under *Daubert* and the ultimate question of whether there is legally sufficient evidence of causation").

[57] *Rizzitiello v. McDonald's Corp.*, 868 A.2d 825, 828-829 (Del. 2005).

[58] As explained above, Plaintiffs respectfully maintain that their claims would have survived a summary judgment motion had AMD so moved at the proper juncture, even if *Havner* were considered in connection with such a motion. However, AMD's failure to so move prevents appellate review of that issue.

Daubert proceedings deprived Plaintiffs of their constitutional rights. As the Reference Manual on Scientific Evidence cautions:

> There are ... consequences to conflating admissibility and sufficiency. The *de novo* standard of review that ordinarily applies to judgments as a matter of law following a determination of insufficient evidence is converted into the lower abuse-of-discretion standard that governs evidentiary rulings on admissibility, and thereby undermines the jury trial mandate of the Seventh Amendment.[59]

Having satisfied *Daubert*, Plaintiffs were entitled to present Dr. Frazier's opinions to a jury. Precluding her testimony not only compromised gravely injured Plaintiffs' rights, but did so in a manner that ostensibly insulated a legally flawed ruling under an abuse-of-discretion standard. This too was improper and warrants reversal.

3. Dr. Frazier's Testimony Satisfied *Havner*

Finally, even if Texas law governed the *Daubert* proceedings, that would offer no basis for exclusion. *Havner* expressly rejected the idea of a "litmus test" requiring epidemiological studies with relative risks of 2.0.[60] Moreover, even if that were not the case, multiple statistically significant epidemiological studies with such numbers supported Dr. Frazier's opinions. [*See* A509-549]. As explained, they included the Lin and Sung Studies for the Ontiveros case, both of which studied heart anomalies in male workers' offspring, and had statistically significant findings with odds ratios well over 2 [A1036-1046]. For Jake Tumlinson, Dr. Cordier's peer-reviewed research also found odds ratios of two or higher for both multiple anomalies

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[59] Reference Manual on Scientific Evidence (3d ed.), at 21.
[60] *Havner*, 953 S.W.2d at 718.

and anomalies from which Jake suffers [A546-547; 1047-1062]. Dr. Khattak's research likewise found a relative risk of 13 for pregnant women occupationally exposed to organic solvents, such as Wendolyn Tumlinson [A547; A1274-1277]. These findings are further supported by the three semiconductor industry-sponsored studies, giving rise to numerous peer-reviewed articles, with statistically significant elevations in miscarriages and odds ratios of 2.0 or higher [A244-258; A537-541]. As explained above, the extensive data respecting spontaneous abortions strongly supported Dr. Frazier's opinions on causation in this action [A244; A494; A1234-1269; A1355-56].

AMD will likely attempt to invoke an abuse-of-discretion standard to argue that the Superior Court acted within its discretion in rejecting as irrelevant every single study considered by Dr. Frazier. However, even if the legal decision to apply Texas law to *Daubert* hearings were correct (which it was not), this Court would still be required to review the fact findings "to determine if they are supported by the record and are the product of a logical and orderly reasoning process."[61] As demonstrated *supra*, at pp. 10-15, the Superior Court's findings rested on a host of factual errors concerning the parents' exposures, and the scientific evidence presented by Dr. Frazier. Strikingly, the Court made those erroneous findings by rejecting outright the testimony of an accomplished and credible physician and epidemiologist, who employed well-accepted methodology with the same rigor and thoroughness demonstrated in her professional

[61] *GMC v. Grenier*, 981 A.2d 524, 528 (Del. 2009)(citation and quotation omitted).

and scholarly activities. Presented with such a witness, and with no defense expert disputing either the propriety of her methods or the wealth of literature supporting her conclusions, the Superior Court nonetheless rendered findings at complete odds with the record. This too warrants reversal.[62]

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the orders dated July 23, 2010 and January 6, 2012 be reversed, and that the Superior Court be directed to enter an order a) reinstating the action, b) denying AMD's motion to exclude Dr. Frazier, and c) denying AMD's motion to apply Texas law.

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[62] Furthermore, even if Texas' preference for studies with odds ratios of 2.0 were relevant to certain *Daubert* hearings, no such showing was required here. As the District Court explained in *Stafford v. Weight Watchers Inc.*, *Havner* was meant to apply to causation opinions, such as those involving Bendectin, for which "there is no obvious reason . . . why [it] should be so." 478 F. Supp.2d 624, 633 (S.D.N.Y. 2007). Here, links between the causation chemicals and birth defects are readily believable and biologically plausible in light of extensive toxicological studies, evidence showing their ability to cause genetic damage, and the well-recognized connection between miscarriages and birth defects [A1381-1387]. This too warrants reversal.