ISSUES BEYOND EXPERTISE --

A HISTORY OF *DAUBERT* AND OTHER DETAILS THAT DRIVE INTERACTIONS BETWEEN LITIGATORS AND EXPERTS

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ISSUES BEYOND EXPERTISE – A HISTORY OF *DAUBERT* AND HOW IT GUIDES SUCCESSFUL STRATEGIES FOR THE FUTURE

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INTRODUCTION

The history of judicial gatekeeping is rooted in Federal Rule of Evidence 702, but driven by the seminal case of *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588 (1993), and its progeny. Come 2018, *Daubert* and the struggle between junk science and judicial control will have been around for 25 years. There have been millions of depositions, motions, trial challenges, judicial opinions, and commentaries aimed at defining and using the *Daubert* gatekeeping function to maintain some control over what "expert" evidence should be evaluated by a jury of our peers.

A review of cases throughout this storied history can be like examining a bowl of crystals, assessing each one individually to glean some common and collective guidance. So in an attempt to maintain sanity, our review is limited to recent years and focused on deciphering successful strategies and practical tools that could be used by defense practitioners at any point in the *Daubert* process. The bottom line lesson is to focus on specific points of attack and to KEEP IT SIMPLE.

Michelle Fujimoto practices in the products liability arena, with a focus on pharmaceutical and medical device defense. She has more than 25 years of experience in complex products liability, toxic tort, and various science-driven litigations, and in the defense of mass tort litigation at a national level. Ms. Fujimoto also provides risk management assessment and best practices counseling to clients ranging from start-up to Fortune 500 companies. Ms. Fujimoto's undergraduate degree is from Pepperdine University and her law degree is from University of Southern California Center for Law.

Pamela J. Yates co-chairs the firm's Product Liability Litigation practice group. Ms. Yates is a highly successful life sciences and product liability trial lawyer internationally recognized as a "Life Science Star." She tries cases in multiple state and federal court venues, and has extensive experience in MDL and class action work. Ms. Yates has successfully acted as national coordinating counsel in various mass tort cases, responsible for all aspects of litigation, including trial, trial preparation and strategy, science, and overall Daubert strategy. Successfully defending pharmaceutical companies began early in her career when, as a young associate, Pam drafted the summary judgment motion in Daubert, leading to the US Supreme Court's decision that ultimately set the standard for challenging the admissibility of expert testimony

THE DAUBERT TRILOGY

Federal Rule of Evidence 702 addresses both the qualifications and admissibility of an expert's opinions. It includes specific requirements meant to ensure the reliability and relevance of an expert's testimony. Rule 702 now states that an expert's opinions are admissible if: (1) the testimony is based upon sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the witness has applied the principles and methods reliably to the facts of the case. Interpretation and application of Rule 702 takes many forms, but is central to the *Daubert* analysis and any challenges thereunder. A brief look back at the *Daubert* trilogy of cases that set the stage for our current practices is a necessary predicate to understanding the most successful *Daubert* strategies.

A. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*

In *Daubert,* the Supreme Court rejected the "general acceptance" test for expert admissibility set out in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). The Supreme Court held that the trial court is the "gatekeeper" of expert testimony and that it is obligated to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. at 589. It was explicitly recognized that judges—not juries—are best suited to evaluate expert testimony because such testimony "can be both powerful and quite misleading." *Id.* at 595.

The fundamental points made by the *Daubert* court are straightforward:

First, expert testimony is not relevant unless it is sufficiently tied to the facts of the case. Satisfying Rule 702 requires "a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 591-92. This required link between theory and case facts is often called "fit." *Id.* at 591; *see also United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985) (coining term).

Second, the *Daubert* Court held that, in assessing reliability, a trial court must ascertain whether an expert's proposed testimony is grounded "in the methods and procedures of science." *Id.* at 590. To help trial courts make this assessment, four factors should be considered:

(1) Whether the theory in question can be and has been empirically tested;

(2) Whether the theory in question has been subjected to peer review and publication;

(3) Known or potential error rate and whether that rate is acceptable; and

(4) Whether the theory is generally accepted in the scientific community.

Id. at 593-95.

Third, these factors are not meant to be exhaustive or exclusive. ("[W]e do not presume to set out a definitive checklist or test."). *Id.* At 593. Justice Blackmun's comments and case law throughout the last two decades indicate that special emphasis is often placed on the first two factors -- has the method been empirically tested and subjected to peer review and publication? In addition, although the *Daubert* holding technically displaced the *Frye* "general acceptance" test as the measure for scientific gatekeeping, it retained "general acceptance" as one of the non-exclusive factors to be considered on the issue of reliability.

B. *General Electric Co. v. Joiner*

The second case of the *Daubert* trilogy is *General Electric Co. v. Joiner*, 522 U.S. 136 (1997). In *Joiner*, the trial court applied *Daubert* and excluded the opinions of the plaintiff's experts, holding that the experts did not reliably establish a causal link between the plaintiff's cancer and his PCB exposure. *Joiner v. Gen. Elec. Co.*, 864 F. Supp. 1310, 1316 (N.D. Ga. 1994). This was overturned on appeal by the Eleventh Circuit Court of Appeals on the grounds that "the Federal Rules of Evidence governing expert testimony display a preference for admissibility....and a particularly stringent standard of review to the trial judge's exclusion of expert testimony" should be applied. *Joiner v. Gen. Elec. Co.*, 78 F.3d 524, 529 (11th Cir. 1996). The Supreme Court rejected this approach, holding that the correct standard of review is abuse of discretion. *Gen. Elec.*, 522 U.S. at 141-43.

Importantly and on a more substantive level, *Joiner* expanded on the requirement that an expert's scientific data "fit" the facts of the case. On this issue, the Court noted that the plaintiff never explained "how and why the experts could have extrapolated their opinions" from animal studies with no direct correlation to human testing or to the specific facts of the plaintiff's PCB exposure. *Id.* at 144. So the expert's methodology was not the only focus. The *Joiner* Court recognized that "conclusions and methodology are not entirely distinct from one another." *Id.* at 146. In other words, where there is an "analytical gap" between the underlying science and the expert's opinion, the opinion is properly excluded. *Id.*

C. *Kumho Tire Co., Ltd. v. Carmichael*

The third case in the trilogy is *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999). Like the first two cases, *Kumho Tire* was a product liability case. The plaintiffs brought suit against a tire manufacturer arising out of a fatal car accident. *Id.* at 142.

At the trial court level, the case was dismissed on summary judgment, after the district court found plaintiffs' expert's opinions to be lacking in both reliability and relevance under the *Daubert* analysis. *Carmichael v. Samyang Tires, Inc.*, 923 F. Supp. 1514 (S.D. Ala. 1996). On appeal, the Eleventh Circuit reversed, holding that *Daubert* applies only to "scientific" testimony—not to the testimony of tire experts, engineers, and others outside the confines of the sciences. *Carmichael v. Samyang Tires, Inc.*, 131 F.3d

1433, 1435 (11th Cir. 1997) (noting that the plaintiffs' tire expert "makes no pretense of basing his opinion on any scientific theory of physics or chemistry").

The Supreme Court unanimously rejected this approach and held that *Daubert* applies to *all* expert testimony. *Kumho Tire*, 526 U.S. at 147 (noting that Federal Rule of Evidence 702 is not limited to scientific testimony but covers all testimony based on "scientific, technical, or other specialized knowledge") (citing Fed. R. Evid. 702). This opinion solidified the breadth and reach of *Daubert*, reaffirmed the importance of proper methodology, and raised the bar on judicial scrutiny of expert evidence. *See id.* at 143.

In our era of "junk science," the *Kumho* focus on holding courtroom science to real world standards is a game-changer. On the issue of reliability, *Kumho Tire* held that the objective of *Daubert*'s gatekeeping requirement is to ensure that courtroom experts adhere to the same reliable principles and methodologies as experts practicing in the field:

> It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.

Id. at 152.

In other words, there should not be a divergence between courtroom science and real world science. *Kumho Tire* also underscored the importance of the "fit" between an expert's underlying theory or technique and specific case facts. The Court held that the correct analysis was not to examine the expert's methodology in general, but to examine his methodology as applied to the specific facts of the case. On this matter, Justice Breyer wrote that "the specific issue before the court was not the reasonableness *in general* of a tire expert's use of a visual and tactile inspection . . . [but] whether the expert could reliably determine the cause of *this* tire's separation." *Id.* at 153-54 (emphasis in original).

SUCCESSFUL *DAUBERT* STRATEGIES

In the past 25 years, there have been thousands of case opinions, published and unpublished, addressing *Daubert* challenges in some context. In the past few years, there have been more than 800 published and unpublished opinions addressing *Daubert* in any given year, with the vast majority (over 600 each year) being in the pharmaceutical or medical device arena. Attempting to exclude expert testimony is a road frequently traveled and often challenged at the appellate level.

In the first half of 2017, there were four product liability cases of interest – two unintended acceleration cases (*Adams* v. *Toyota Motor Corp.*, No. 15-2507, 2017 WL 2485204 (8th Cir. June 9, 2017; *Nease v. Ford Motor Co.*, 848 F. 3d 219 (4th Cir. 2017)) and two drug cases *(In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.* No. 16-2247, 2017 WL 2385279 (3d Cir. June 2, 2017; *Wendell v. GlaxoSmithKline LLC*, No. 14-16321,

2017 WL 2381122 (9th Cir. June 2, 2017)). In all four cases, the defendants' *Daubert* challenges were rejected at the appellate level. Not a good year thus far, but the message seems to be that *Daubert* is flexible and unpredictable. The year before, 2016, was notable for a palpable uptick in *Daubert* challenges to financial experts, with a good percentage of them being excluded. But it was 2015 that proved to be a banner year (from my perspective and a defense perspective) in terms of cases that were strategically instructive on how to advance a successful *Daubert* attack. In 2015 alone, there were more than 600 published and unpublished federal judicial opinions that addressed *Daubert* challenges in the pharmaceutical and medical device arena. There were about 140 published opinions, far too many to discuss in one paper. However, of those published opinions, a few stood out as directly addressing major *Daubert* challenges and particular strategies that proved successful. The top 5 successful strategies gleaned from these cases are:

1. Go Latin and argue ***IPSE DIXIT*** (Latin for "He himself said it")—Just because the expert says it's so, does not make it so.

    a. The seminal case recognizing this doctrine is *General Electric Co. v. Joiner*, 522 U.S. 136 (1997). The Supreme Court held that while trained experts commonly extrapolate from existing data, a district court is not required to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. *Id.* at 146. In other words, the expert cannot just identify scientific evidence and then just *say* it supports the proffered opinion. The expert must connect the dots by explaining how the data supports the opinion within the facts of the case. This doctrine has been extended and used in many settings.

    b. *Example*: *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307 (M.D. Fla. 2015): The expert "leapt" from his scientifically supported opinions regarding the causes of IVC filter fracture to his unsupported conclusion that, absent any evidence of fracture, these same deficiencies could cause a filter to tilt, migrate or perforate (which is what occurred in the case). *Id.* at 1321. Thus, his opinion on the cause of tilt, perforation and migration was not sufficiently reliable and, therefore, excluded. *Id.*

    c. *Example*: *In Re Wright Med. Tech. Inc., Conserve Hip Implant Prods. Liab. Litig.*, --- F. Supp. 3d ---, 2015 WL 5117896 (N.D. Ga. 2015): Expert did not provide any specific support for his opinion of metallosis other than relying on the treating physician's opinion that there was metallosis on the plaintiff's hip. *Id.* at *15. The opinion was excluded because the expert did not undertake his own analysis. *Id.* at *15-16. Bootstrapping another's opinion and just "saying it's so" is not sufficient.

2. Attack the bridge between Methodology – Facts – Conclusions. Illuminate the ***Analytical Gaps.***

   a. This is an extension or drilling down on the *ipse dixit* doctrine. The Supreme Court in *Joiner* held that in order to get past *ipse dixit*, the expert must demonstrate how his method connected the facts of the case and then led to his conclusion. The Court stated: "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." 522 U.S. at 146. Thus, it is not abuse of discretion for the district court to exclude testimony based on *ipse dixit*. *Id.*

   b. *Example*: *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307 (M.D. Fla. 2015): The expert was excluded because he could not show what or how the purported design or manufacturing defect that could cause fractures, could also cause tilt, migration or perforation of the IVC filter. *Id.* at 1321.

   c. *Example*: *Burst v. Shell Oil Co.*, 104 F. Supp. 3d 773 (E.D. La. 2015): The expert failed to validate his results against other studies. *Id.* at 779, 786. Also, expert based his assumptions on calculations that were inconsistent with the factual record. *Id.* at 784-85.

   d. *Example*: *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827 (7th Cir. 2015): The experts failed to connect the dots from the studies they evaluated to the illnesses suffered by the children in the case. *Id.* at 837.

3. ***Basic geometry*** – Show the expert is trying to fit a square peg (the facts of the case) into a round hole (undisputed or accepted generic opinions).

   a. *Example*: *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307 (M.D. Fla. 2015): Although the IVC filter inside plaintiff's body had not fractured, the expert improperly based his opinion regarding the tilt, migration and perforation of the IVC filter on data and opinions pertaining to mechanisms of fracture. *Id.* at 1321.

4. ***Good Methodology Looks Forward, Not Backward.*** Buildings are constructed from the ground up, not the other way around. Illustrate that the expert's assumptions were constructed *after* the development of his conclusion and only to support his pre-conceived conclusion.

   a. *Example*: *In Re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, --- F. Supp. 3d ---, 2015 WL 7422614 (D.S.C. 2015): The court excluded an expert's opinions because it was obvious the expert

reached a conclusion, and then utilized various methodologies that would yield the results he was looking for in order to support his conclusion. *Id.* at *18.

5. ***Keep in the Comfort Zone*** - Work from the expert's qualifications and create the world in which he must live. The expert's qualifications should be directly applicable to the opinions offered.

    a. *Example*: *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307 (M.D. Fla. 2015): The court recognized that experts cannot opine on negligence, recklessness, ethics, or professionalism if they do not have the sufficient qualifications in those areas (legal, ethics, corporate conduct, etc.). *Id.* at 1325-26.

    b. *Example*: *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749 (S.D. Ohio 2015): Expert was not qualified to opine on regulatory matters, including whether defendant was required to send a patient package leaflet directly to patients or whether defendant's submissions to the FDA should have included certain materials. *Id.* at 773.

PRACTICAL TIPS FOR KEEPING DAUBERT SIMPLE

A strategic plan is one thing, but how do you execute it effectively, whether in deposition or motions to exclude all or some of an expert's testimony? From our perspective, it boils down to KEEP IT SIMPLE. After sorting through scientific complexities, massive amounts of data and literature, and often convoluted methodologies, the best practical tips are the most simple:

1. Pick the issues you win on
2. Don't bite off more than you can chew
3. Credibility is key – maintain your credibility and attack the expert's
4. Be creative

Most of these tools are straightforward, so using them effectively takes creativity. For example, just because an expert uses an unreliable method does not mean it is easily exposed in a deposition. A savvy expert will not only know how to find ways to support her conclusion, but will also be prepared to defend her methodology at deposition. Since courts are not as well-versed in the science as either the expert or the lawyers, many judges

can only look for the expert to provide a plausible explanation for their departure from standard methods. When an expert is prepared to answer why they did what they did, you may need to consider other options.

The use of hypothetical questions may be helpful in this regard. Of course, these questions vary greatly from case to case and need to be tailored to the specific case, but the following question may help you decide how to do so in your case: You wouldn't cite a finding from one study as reliable, but reject other findings from the same study as unreliable? You wouldn't use one methodology to determine causation in this case, and use a different methodology to determine causation in another case involving a different drug?

Many times, an expert who testifies in one case will be designated in future cases involving the same product. Where an expert is offering case-specific opinions, you will not only want to consider the case at hand, but will also want to lock the expert in for future cases. Hypotheticals can be particularly useful for the "next" case where the expert may testify. For example: You agree that you must rule out "X" risk factor in order to determine that this product caused the injury? If Mr. Smith took drug "A", drug "B", and drug "C", how would you know which product caused her injury? If Mrs. Doe only used the medication for less than one month, would that affect your opinion?

Finally, counsel should be prepared to go off script. While it is essential that one is prepared with a detailed outline that attacks the flaws identified in the expert's methodology, merely moving from one scripted question to another may not yield the necessary testimony. Chances are that if the expert is a hired gun, counsel will know the science better than the expert will. So when the expert fails to adequately answer a question, don't just ask it over and over again, and do not just move on. Be prepared to fight. When the science is strong enough to file a *Daubert* motion, counsel needs to know it and must consider where the expert dug him or herself a new hole with each answer. So, if the expert rejects one finding because the study had a certain flaw, counsel needs to know which of the studies the expert relied on that have the same flaw. When an expert relies on a non-significant finding in support of her opinion, counsel will need to know which non-significant findings refute her opinion. At the end of the day, this may or may not accomplish what is needed for a *Daubert* motion, but if it doesn't, it will develop useful material for trial. Whatever the outcome of the fight at the expert's deposition, you are not going to lose points, you can only gain them.

APPENDIX I: Summaries of the key facts and *Daubert* rulings of the representative cases cited in the text follow:

Tillman v. C.R. Bard, Inc.
96 F. Supp. 3d 1307 (M.D. Fla. 2015)

Background:

Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. design and manufacture an inferior vena cava filter known as the G2 filter. In February 2008, a physician implanted the G2 filter into plaintiff's body. Although the filter was intended to be removed at a later point, it changed position within plaintiff's body such that it cannot be removed safely.

Plaintiff asserts negligence, and strict liability for failure to warn, design defect, and manufacturing defect. Plaintiff alleges the filter is defective and, because it cannot be removed, it exposes her to ongoing risk of serious harm for which she requires medical monitoring. Before the court are defendants' motions to exclude the testimony of plaintiff's expert witnesses.

Analysis:

Expert Witness: Dr. Robert Ritchie

- Admissible – Opinion regarding fracture in G2 filters. Evidence that G2 filters are prone to fracture due to design of manufacturing defect is relevant to plaintiff's claim for medical monitoring damages, that plaintiff is exposed to an ongoing present danger with the filter inside her body.
- Excluded – Opinion regarding the cause of tilt, perforation and migration. Ritchie's contention that the defects cause fracture does not support his conclusion that the defects cause tilt, migration and perforation. He does not discuss what or how the purported design or manufacturing defects can also cause tilt, migration or perforation.

Expert Witnesses: Dr. Robert M. McMeeking & Dr. Matthew R. Begley

- Admissible – Opinion on filter fatigue and fracture. It is relevant to plaintiff obtaining ongoing medical monitoring (as discussed with Ritchie).
- Admissible – Opinion regarding inadequate testing. It would be helpful to a jury in determining a fact in issue, specifically whether Bard breached its duty of care in designing the G2 filter, or failed to issue adequate warnings.
- Admissible – Opinion that the testing Bard performed was incompetent. Experts are qualified to opine on competence as a matter of engineering and design principles.
- Admissible – Opinion that it is misleading for Bard to claim that G2 filters are more fatigue resistant than Recovery filters. The scientific data supporting the claim made regarding the G2 filters is within the realm of the experts' expertise and would be helpful to the jury.

- Excluded – Opinion regarding Bard's manufacturing controls. While the experts are qualified to opine on mechanical failure and stress-strain analysis, they do not identify any qualifications specific to the area of manufacturing controls and processes.
- Excluded – Opinion that Bard acted negligently or recklessly. These terms have legal meaning, and the experts do not indicate what standard of care they are applying to reach this opinion nor does plaintiff explain how these experts are qualified to opine on the applicable standard of care.
- Excluded – Opinion that Bard's conduct was unethical and unprofessional. Plaintiff does not show that the experts are qualified to opine on the ethical or professional standards in the industry, and she does not show how this opinion is reliable or relevant to the case.

Expert Witness: Dr. William A. Hyman

- Admissible – Opinion on FDA guidelines and regulations. It will be helpful for the jury understand the complex regulatory framework that informs the standard of care in the medical device industry.
- Excluded – Opinion on the adequacy of Bard's warnings. Hyman has never drafted an entire instructions for use, nor has he reviewed the warnings or labeling of other IVC filters.
- Excluded – Opinion on the testing, design and warnings. Hyman did not conduct any tests, examine a Bard G2 filter or any other type of IVC filter, and has never seen in person or touched an IVC filter. He also concludes that the G2 filter is defective without assessing the risks versus the benefits of the filter, the availability and safety profiles of other filters on the market, or the viability of a safer, alternative design.

Expert Witness: Dr. Michael Freeman

- Admissible – Opinion that Bard's filters were failing at an "alarmingly high" rate. Bard's criticisms of Freeman's opinion are more appropriately directed to the weight, rather than the admissibility of this evidence.
- Excluded – Opinion on Bard's corporate conduct or how Bard should have responded to the data in its possession. Freeman is not qualified to opine about the market of the medical device industry.

Conclusion:

Court granted in part and denied in part Bard's *Daubert* motions.

Burst v. Shell Oil Co.
104 F. Supp. 3d 773 (E.D. La. 2015)

Background:

Plaintiff's husband worked at gas stations operated by Shell, Chevron, and Texaco from 1958 through 1971, where he would regularly come into contact with gasoline containing benzene. In June 2013, at age 71, plaintiff's husband was diagnosed with acute myeloid leukemia. In December 2013, plaintiff's husband passed away due to the leukemia.

Plaintiff filed this products liability action against defendants, alleging that her husband's regular exposure to gasoline containing benzene during the years he worked at the gas stations caused his leukemia. She alleges that defendants negligently manufactured and sold products containing benzene and they negligently failed to warn foreseeable users about the health hazards associated with benzene. Before the court is defendants' motion to exclude the testimony of plaintiff's expert witness.

Analysis:

Expert Witness: Richard Miller

- Excluded – Miller's estimate of the decedent's benzene exposure from inhaling gasoline evaporated from the parts-washing bucket is unreliable. He failed to validate his results against other studies showing that the corresponding gasoline vapor levels required to expose a person to that much benzene would be lethal.
- Excluded – Miller's amended opinion is also unreliable. He made his calculations without any attempt to validate his results, and the evidence was inconsistent with his conclusion.
- Excluded – Miller's estimate of the decedent's dermal exposure to benzene from washing parts is unreliable. He bases his assumptions on calculations that are inconsistent with the factual record, and he fails to account for evaporation.
- Excluded – Miller's estimate for the decedent's benzene exposure from inhaling gasoline vapors while washing parts is unreliable. He relied solely on the self-reported symptoms from plaintiff from almost 50 years ago without showing this was a reliable methodology, and he failed to validate his results against scientific literature measuring actual exposure levels.

Conclusion:

Court granted defendants' motion to exclude Miller's testimony.

Rheinfrank v. Abbott Laboratories, Inc.
119 F. Supp. 3d 749 (S.D. Ohio 2015)

Background:

Defendants Abbott Laboratories, Inc. and Abbvie Inc. manufacture, market, and distribute Depakote, an antiepileptic drug. In 1988, plaintiff was prescribed Depakote to treat her epilepsy and continued to ingest it during her pregnancy. When her daughter was born in 2004, her daughter was diagnosed with congenital malformations, facial dysmorphisms, cognitive impairment, developmental delay, and Fetal Valproate Syndrome. Plaintiff attributes her daughter's injuries to her use of Depakote while pregnant.

Plaintiffs filed this products liability and negligence action in 2013. Many related cases are pending throughout the country. Before the court are the parties' cross-motions for summary judgment; a challenge to plaintiff's expert witness was included in the summary judgment motion.

Analysis:

Expert Witness: Dr. Michael D. Privitera

- Admissible – Opinion on the medical facts and science regarding the risks and benefits of Depakote and comparing that knowledge with what was provided in the text of the labeling.
- Excluded – Opinion about the regulatory aspects of the case. Privitera is not qualified to opine on regulation matters, including whether Abbott was required to send a patient package leaflet directly to patients or whether Abbott's submissions to the FDA should have included certain materials.

Conclusion:

Court granted in part and denied in part defendants' motion for summary judgment. Court denied plaintiff's motion for partial summary judgment.

C.W. ex rel. Wood v. Textron, Inc.
807 F.3d 827 (7th Cir. 2015)

Background:

From1954 to 2006, Textron operated a fastener manufacturing plant in Indiana. During its operations, the plant released vinyl chloride – a toxic gas that would eventually seep into the ground water. Plaintiffs lived nearby and were affected by the vinyl chloride;

their children experienced gastrointestinal issues, immunological issues, and neurological issues.

Plaintiffs filed this products liability action against defendant. As to plaintiffs' expert witnesses, the district court excluded them on the ground that they did not use reliable bases to support their opinions. The district court then granted summary judgment in favor of Textron because without the experts' opinions, plaintiffs could not prove general and specific causation, which are required in a toxic tort case. This appeal is whether the district court abused its discretion in excluding plaintiffs' experts based on the reliability of their methodology.

Expert Witnesses Evaluated by the District Court:

- Dr. James G. Dahlgren – Excluded his testimony because his methodology was unreliable. He could not rely on regulatory exceedances to demonstrate causation, and he failed to connect the dots between the scientific studies that he analyzed and the opinions that he offered.
- Dr. Vera S. Byers – Excluded her testimony because the studies she relied on were too attenuated, and she failed to adequately extrapolate from them.
- Dr. Jill E. Ryer-Powder – Excluded her testimony because she relied on regulatory exceedances to formulate her opinion as to causation. She also relied on attenuated studies concerning much higher exposure levels, and failed to extrapolate from those studies.

Analysis:

- Plaintiff's experts failed to connect the dots from the studies they evaluated to the illnesses endured by the children, and the studies they relied on were too attenuated.
- Even if there is a dearth in scientific literature about a particular topic, there are other alternatives. Scientists have developed computer-based models to extrapolate from animal data to human subjects, and from high doses to lower doses.
- The experts' differential etiology is unreliable. Dahlgren's differential etiology does not present the reliability that *Daubert* demands. Byers's differential etiology was flawed because it ruled vinyl chloride as a cause in the first place, without the benefit of analogous studies and an acceptable method of extrapolation. Ryer-Powder's argument that the levels of vinyl chloride exceeded government regulation does not, by itself, prove causation.

CONCLUSION:

District court did not abuse its discretion in excluding plaintiffs' experts.

In re Wright Medical Technology Inc., Conserve Hip Implant Products Liability Litigation
--- F. Supp. 3d ---, 2015 WL 5117896 (N.D. Ga. 2015)

Background:

In 1995, Dr. Lynn G. Rasmussen completed a total hip revision surgery on plaintiff's left hip, utilizing a ceramic femoral ball and a polyethylene liner in a metal acetabular shell. Rasmussen later told plaintiff she met the criteria for a total hip replacement of her right hip, and recommended replacement with the Conserve Hip Implant System. In April 2006, Rasmussen implanted the Conserve implant system into plaintiff's right hip. In October 2012, plaintiff was doing yoga when she felt an immediate, severe pain in her right hip and groin. Rasmussen performed a revision surgery in October 2012.

Defendants Wright Medical Technology, Inc. and Wright Medical Group, Inc. designed the Conserve Hip Implant System. Plaintiff sued defendants for product liability, negligence, and misrepresentation. She asserts the design of the system was defective and dangerous because it omits a liner separating the cobalt/chromium acetabular cup from the cobalt/chromium femoral head, resulting in the creation of metal-on-metal wear debris. Before the court are Wright's *Daubert* motions to exclude the testimony of plaintiff's expert witnesses.

Analysis:

Testimony Relating to Metallosis:

- Plaintiff contends she suffered from metallosis as a result of the abrasion of components of the Conserve Hip Implant System. The question central to exclude the experts' testimony is whether they may rely on the clinical observations and opinions of Rasmussen that there were signs of a metallosis reaction of her hip with an inflammatory synovium and that the acetabulum was exposed and that it was cleaned of the soft tissue debris from the metallosis reaction.
- Admissible – Rasmussen's observations and opinions are reliable because of his considerable background and experience in hip replacement and revision surgeries, the number of instances where he recognized and diagnosed metallosis, and his credentials and qualifications as an expert in original and revision hip replacement surgeries. Therefore, plaintiff's experts can rely on Rasmussen's observations, conclusions, and opinion because they are the kind of medically reliable evidence that medical experts would consider in reaching a conclusion about medical conditions or complications.

Expert Witnesses Relying on Rasmussen's Observations and Conclusions About Metallosis:

- Dr. Elizabeth A. Laposata – Admissible. Laposata relies on the observations, conclusions, and opinions Rasmussen made and reached during plaintiff's revision

surgery, plaintiff's medical records, plaintiff's deposition, Laposata's personal examination of photographs of the explanted head and cup, and the explant itself.

- Dr. John D. Jarrell – Admissible. Jarrell reached his opinions based on articulated evidence that supported Rasmussen's conclusion that plaintiff experienced metallosis in the tissue surrounding her hip implant.
- Dr. Reed Ayers – Admissible. To the extent defendants' sole objection to the admissibility of Ayers's expert opinion is that he characterized the tissue discoloration as "staining," which is a term not used in the Operative Report, it is unpersuasive. This reason alone is not a credible reason to exclude testimony.
- Dr. Joel Bach – Admissible. Bach reviewed the Operative Report, plaintiff's medical records, photographs of plaintiff's explanted components, plaintiff's deposition transcript, and certain expert reports.
- Dr. John I. Waldrop – Admissible. Waldrop is an experienced orthopedic surgeon who reviewed plaintiff's medical records, digital x-rays of her original right hip replacement, and photographs of the explant.
- Dr. Brent W. Morgan – Excluded. Morgan does not provide any specific support for his opinion, other than Rasmussen's opinion that there was metallosis in plaintiff's hip. Morgan did not examine any x-rays of the dislocated implant, and is not sure of the extent of the metallosis and what, if any, inflammation it caused in plaintiff's soft tissues. There is an analytical gap between the data upon which he relies and his conclusion.
- Dr. Suzanne Parisian – Excluded. Plaintiff retained Parisian to offer an opinion regarding defendants' compliance with regulatory requirements, thus Parisian cannot opine on causation. Also, plaintiff has not provided sufficient support to establish by a preponderance of the evidence that Parisian's references to Rasmussen's observations, in her capacity as a regulatory expert, will assist the trier of fact in understanding the regulatory matters at issue.

Expert Witness: Dr. Jay M. Vincelli

- Excluded – Opinion regarding his calculation of the immeasurable wear on plaintiff's hip implant. Vincelli's theory cannot be tested in such a way that would show that the actual "immeasurable" wear on an explanted device matched the mathematical calculations he utilized in this case. As a result of the wear being "immeasurable" and Vincelli's methodology not being tested, it cannot ascertain the potential rate of error of his technique. Thus, his methodology is not generally accepted in the scientific community.

Expert Witness: Dr. Reed Ayers

- Admissible – Opinion that chromium contained in a CoCrMoc alloy, such as that used in the Conserve implant, is mobile and will leach out of the device, causing harm to the person with the implant. He linked his findings to the specific design of plaintiff's Conserve hip implant, examined plaintiff's medical records and other expert reports, examined microscopic images of plaintiff's Conserve cup and ball, and found scratches and wear debris on the surfaces of both components.

Expert Witness: Dr. Lance A. Waller

- Excluded – Opinion on revision and failure rates. The studies and standards upon which he bases his opinion are not generally accepted within the scientific community.

Conclusion:

Court granted in part and denied in part Wright's motions to exclude plaintiff's expert testimony.

In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation
--- F. Supp. 3d, 2015 WL 7422613 (D.S.C. 2015)

Background:

In this MDL, plaintiffs allege that Lipitor caused them to develop Type 2 diabetes. Before the court is defendant's motion to exclude the testimony of plaintiff's expert witness.

Analysis:

Expert Witness: Dr. Nicholas Jewell

- Admissible – Opinion about causation. Plaintiff has represented that Jewell will not be offering a causation opinion and his testimony will be limited to his opinions in his report. And, the opinions in his report are confined to very particular data sets. Thus, Jewell's opinion will be admissible to the extent they are confined to the particular data sets laid out in his report.
- Excluded – Opinion that the New Drug Application (NDA) data should have alerted defendant to the possibility of increased risk of new-onset diabetes associated with atorvastatin treatment. Jewell performed statistical tests based on a single elevated glucose measurement, which makes it unreliable. He failed to exclude participants with elevated baseline glucose, which is problematic and makes his finding unreliable. Also, including participants with elevated baseline glucose is contrary to his methodology in his other analyses, which makes his finding unreliable. Lastly, when Jewell did not get a statistically significant result when he calculated his first set of statistics, he turned to a second statistical test. This shows that he reached a conclusion and then did research to support that conclusion.
- Excluded – Opinion, based on the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) data, that there is an association between Lipitor and new-onset diabetes. Jewell's finding is contrary to that of peer-reviewed, published articles. His methodology is flawed because without an explanation, he chose not to run his statistical analysis using adjudicated data. Had he done so, he would have reached

the same conclusion as the authors of the articles showing that the data does not show a statistically significant increase in new-onset diabetes.

Conclusion:

Court excludes Jewell's testimony regarding the NDA data and ASCOT data.

General Electric Company v. Joiner
522 U.S. 136 (1997)

Background:

Respondent Robert Joiner worked as an electrician in the Water & Light Department of Thomasville, Georgia. His job required him to work with and around the City's electrical transformers, which used a mineral-oil-based diaelectric fluid as a coolant. Joiner often had to stick his hands and arms into the fluid to make repairs. Years later, the City discovered that the fluid was contaminated with polychlorinated biphenyls (PCB's). Joiner was diagnosed with small-cell lung cancer, and he sued petitioners who manufactured transformers and dielectric fluid.

Joiner filed his suit in state court, which was subsequently removed to federal court. Petitioners moved for summary judgment on the grounds that there was no admissible scientific evidence that PCB's promoted Joiner's cancer. The District Court granted summary judgment because the testimony of Joiner's experts had failed to show there was a link between exposure to PCB's and small-cell lung cancer. The Eleventh Circuit reversed, holding that the District Court erred in excluding the testimony of Joiner's expert witnesses.

Issue:

What standard should an appellate court apply in reviewing a trial court's decision to admit or exclude expert testimony under *Daubert*?

Analysis:

A. Whether the Eleventh Circuit Applied the Appropriate Standard

- Abuse of discretion is the proper standard of review of a district court's evidentiary rulings. *Daubert* did not alter this general rule.
- While the Federal Rules of Evidence allow district courts to admit a broader range of scientific testimony than would have been admissible under *Frye*, they leave in place the "gatekeeper" role of the trial judge in screening such evidence.

- Therefore, the Eleventh Circuit erred in applying an overly "stringent" review to the exclusion of Joiner's expert testimony. Instead, the Eleventh Circuit should have deferred to the trial court.

B. Whether the District Court Abuse its Discretion in Excluding Joiner's Expert Testimony

- Joiner's theory of liability was that his exposure to PCB's and their derivatives "promoted" his development of small-cell lung cancer. In support of that theory he proffered the deposition testimony of expert witnesses: (1) Dr. Arnold Schecter testified that he believed it was more likely than not that Joiner's lung cancer was causally linked to cigarette smoking and PCB exposure; and (2) Dr. Daniel Teitelbaum testified that Joiner's lung cancer was caused by or contributed to in a significant degree by the materials with which he worked.
- *Animal Studies:* The District Court agreed with petitioners that the animal studies on which the experts relied did not support his contention that exposure to PCB's had contributed to his cancer. The studies were so dissimilar to the facts presented in this litigation that it was not an abuse of discretion for the District Court to have rejected the experts' reliance on them.
- *Epidemiological Studies:* The District Court also concluded that the four epidemiological studies on which respondent relied were not a sufficient basis for the experts' opinions. The authors of the study were unwilling to say that PCB exposure had caused cancer among the workers they examined, thus their study did not support the experts' conclusion that Joiner's exposure to PCB's caused his cancer. In another study, the authors did not suggest a link between the increase in lung cancer deaths and the exposure to PCB's. Other studies were similarly unpersuasive.
- Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.
- Therefore, it was within the District Court's discretion to conclude that the studies upon which the experts relied were not sufficient, whether individually or in combination, to support their conclusions that Joiner's exposure to PCB's contributed to his cancer.

Conclusion:

The appropriate standard is abuse of discretion. The District Court did not abuse its discretion in excluding expert testimony