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The Voice

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This Week's Feature

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By Robin Shah

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—Naguib Mahfouz (b. Dec. 11, 1911).

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Plaintiffs' General Causation Expert Is Excluded: Now What?

By Robin Shah

In product liability cases involving complex medical and scientific issues, plaintiffs are typically required to offer expert testimony to establish general causation because the issue of causation is beyond the knowledge of a lay jury.

If defendants are successful in excluding plaintiffs' general causation expert under *Daubert* or similar standards, courts commonly grant summary judgment for the manufacturer because without the requisite expert testimony, there is no genuine issue of material fact pertaining to causation. *See, e.g., C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 838 (7th Cir. 2015) ("With no experts to prove causation…summary judgment in this case was proper."); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 956 (D. Minn. 2009) ("[A]bsent an admissible general causation [expert] opinion, Plaintiffs' claims necessarily fail and… summary judgment must be granted."); *In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d 567, 579 (S.D.N.Y. 2006) (same).

However, in recent years, plaintiffs have tried to circumvent *Daubert* rulings by arguing that there is enough non-expert evidence to establish general causation and deny summary judgment for defendants. Courts are reluctant to allow such an end-run around the need for scientific expert testimony in complex cases and have rejected such attempts by finding that the following categories of information are not adequate substitutes for expert testimony.

Adverse Event Reports

Some plaintiffs have argued that adverse event reports are enough to establish a causal relationship between the product and the injury reported. For instance, in *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, the plaintiffs cited reports in which doctors or patients suggested that incidents of birth defects occurred after using Zoloft. 176 F. Supp. 3d 483, 494 (E.D. Pa. 2016), *aff'd sub nom. In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017). In granting summary judgment for Pfizer, the court noted that "[a]lthough a court may rely on anecdotal evidence such as case reports, courts must consider that case reports are merely accounts of medical events. They reflect only reported data, not scientific methodology" that can point to causation. *Id.* at 497.

Similarly, in *Vallejo v. Amgen, Inc.*, the court rejected the plaintiffs' argument that a MedWatch report established a causal connection that obviated the need for an expert. 274 F. Supp. 3d 922, 926 (D. Neb. 2017), *aff'd*, 903 F.3d 733 (8th Cir. 2018). The court found that "[a]t most, the report suggests a 'temporal association' between the pharmaceutical product and the reported medical event of an individual who has no relation to the present dispute." But that association was not "scientifically valid proof of causation" and did not constitute a proper substitute for expert testimony. *Id.* (citation omitted).

Product Labels

Courts have similarly refused to accept plaintiffs' arguments that product labels, either of the product at issue or related products, amount to party admissions that can prove general causation. For example, in *Coleson v. Janssen Pharm., Inc.*, the court granted summary judgment for Janssen and found that Risperdal's warning label discussing the injury at issue could not defeat summary judgment because "[p]roduct warning labels can have over-inclusive information on them," and warning about a potential event does not equate to causation. 251 F. Supp. 3d 716, 723 (S.D.N.Y. 2017). Similarly, in *In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II),* the court found that the label on another contraceptive product indicating that the applicable injury had been reported in rare occasions did not support a finding of causation. Instead, the court held that the warning merely revealed the existence of historical case reports and a decision to err on the side of caution by warning about a rare event. 387 F. Supp. 3d 323, 356 (S.D.N.Y. 2019).

Medical Literature

Courts have also drawn distinctions between studies finding correlation versus causation, finding that providing a jury with evidence of the former in lieu of expert testimony would be improper. In *In re Mirena*, the plaintiffs argued that a study evidenced a statistically significant association between Mirena and the alleged injury that would allow the jury to find general causation. 387 F. Supp. 3d at 344. The court disagreed and held that "the Valenzuela study showed nothing more than a correlation, subject to iden-

tifiable confounders, between Mirena and IIH [idiopathic intracranial hypertension]." *Id.* Accordingly, the court concluded that the study "could not be relied on as proof of general causation[.]" *Id.* *See also In re Zoloft*, 858 F.3d at 497 (finding that internal communications about epidemiological studies only demonstrated that Pfizer employees were raising questions about the "association" between Zoloft and birth defects as opposed to proving causation).

Previously Excluded Testimony

Finally, some plaintiffs have essentially ignored *Daubert* rulings altogether and tried to resurrect pieces of the previously excluded expert testimony that they consider to be non-controversial. In *In re Mirena*, the court responded with incredulity and held that the "end-run around Rule 702—and th[e] Court's Daubert ruling—is unsustainable." 387 F. Supp. 3d at 344. In that case, the court rejected the plaintiffs' argument that a lay person could draw on aspects of the previously excluded testimony to conclude that Mirena is a cause of idiopathic intracranial hypertension. The court held that "even assuming *arguendo* that various scientific propositions nestled within plaintiffs' experts' reports were, largely, scientifically uncontested," they could not be "revived as fodder from which a lay jury could speculate about and derive a theory of general causation." *Id.* The court specifically admonished the plaintiffs for their "backdoor means" to revive the excluded expert analyses.

Conclusion

In sum, defendants should be vigilant for an attempt by plaintiffs to defeat summary judgment after favorable *Daubert* rulings by arguing that non-expert evidence can demonstrate general causation. Fortunately, courts have been hesitant to accept the various types of evidence advanced by plaintiffs, and plaintiffs certainly face a steep uphill battle in identifying non-expert evidence that can pass muster in lieu of traditional expert testimony.

Robin Shah is a counsel in **Skadden Arps Slate Meagher & Flom LLP's** Mass Torts, Insurance and Consumer Litigation Group in New York. Ms. Shah represents an array of clients, including medical device manufacturers, consumer product manufacturers, and pharmaceutical companies in complex civil litigation in state and federal courts across the country. She advises clients on all aspects of litigation, including pre-trial discovery, factual investigation, fact and expert witness preparation, and trial strategy. Ms. Shah is a member of the DRI Young Lawyers Committee.

Keep The Defense Wins Coming!

Please send 250–500 word summaries of your "wins," including the case name, your firm name, your firm position, city of practice, and e-mail address, in Word format, along with a recent color photo as an attachment (.jpg or .tiff), highest resolution file possible (*minimum* 300 ppi), to DefenseWins@dri.org. Please note that DRI membership is a prerequisite to be listed in "And the Defense Wins," and it may take several weeks for *The Voice* to publish your win.

Paul G. Cereghini, William F. Auther, Hannah L. Mohrman, and Nathan J. Marcusen




After a four-week trial and nearly a week of deliberations, a civil jury returned a complete defense verdict for American Honda Motor Co., Inc., in a $160 million all-terrain vehicle product liability case, Chelsea Rush et al. v. American Honda Motor Co., Inc., et al., Los Angeles County Superior Court, Case No. BC658021, the Honorable Victor E. Chavez presiding.

American Honda was represented by its lead counsel, Paul G. Cereghini of Bowman and Brooke in Phoenix, Arizona, as well as William F. Auther of Bowman and Brooke in Phoenix, Arizona, Hannah L. Mohrman of Bowman and Brooke in Los Angeles, California, and Nathan J. Marcusen of Bowman and Brooke in Minneapolis, Minnesota. Paul Cereghini is Bowman and Brooke's firm chair.

The suit arose from a single-vehicle crash that occurred on February 29, 2016, in the Ocotillo Wells State Vehicular Recreation Area. The plaintiff, who was twenty-four years old and two months pregnant, rented a 2008 Honda TRX250EX ATV to go trail riding with her boyfriend. As she entered a wash on the Crossover Trail, the plaintiff suddenly veered off the trail, careened down an embankment, and collided with a cliff wall. She sustained multiple cervical-spine fractures as a result of which she is an incomplete quadriplegic.

The plaintiff alleged that she crashed the rental ATV due to defects in its design and warnings. Specifically, she claimed that her right foot came off the ATV's right foot peg and made contact with the right rear tire, causing her to lose control and veer off the trail. She alleged that the TRX250EX lacks an adequate foot environment to prevent riders' feet from contacting the rear tires. She also alleged that American Honda failed to warn adequately about the need for riders to keep their feet on the foot pegs. Based on these allegations, she pleaded claims of strict liability design defect, negligent design defect, strict liability failure to warn, and negligent failure to warn. She asked the jury to award up to $160 million.

American Honda vigorously defended the TRX250EX's design and warnings. A Honda engineer testified about the company's rigorous development history, which included over 20,000 of actual running tests. American Honda's experts explained that the ATV's foot environment and labeling satisfy the requirements of the American National Standard for Four Wheel All-Terrain Vehicles, which is now a mandatory federal safety standard. Honda witnesses also testified about the TRX250EX's state-of-the-art foot environment design and exemplary safety record.

As for plaintiff's crash, American Honda presented evidence that the plaintiff's foot did not get caught in the ATV's rear tire and that the crash resulted not from any design or warnings flaw but from improper operation. The jury heard evidence that as the plaintiff approached the rough terrain through the wash where the crash occurred, she was in the lead for the first time, was fatigued, had a sore right wrist, and was distracted by concerns about a large rock ahead of her and her companion's whereabouts behind her. American Honda's crash reconstructionist explained that these factors, as well as the plaintiff's lack of experience, combined to cause plaintiff to veer off the trail.

The jury rejected all of plaintiff's criticisms of American Honda and its product, and their verdict.

DTCI Supports Amethyst House

During the Annual Conference of the **Defense Trial Counsel for Indiana** (DTCI), members raised funds and donated personal care items for the Amethyst House, Inc., a non-profit United Way Agency that provides residential and outpatient services for persons dealing with drug and alcohol addiction and gambling issues.

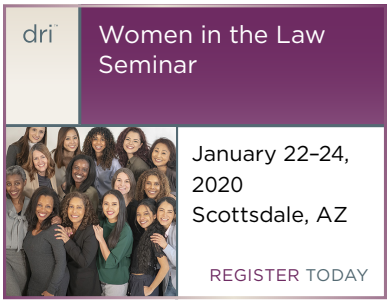
From left: Desirae Draluck, Amethyst House; Jordan Slusher, DTCI Young Lawyer Committee Chair; Kiki Dunn, Amethyst House; Jim Hehner, DRI Indiana State Representative; Renee Mortimer, DTCI President; Don Smith, DTCI President-Elect.

#GoldenCoatDrive: The Need for Warmth

#DRICares is hosting its second annual **SLDO Golden Coat Drive Competition**! From December 1 to December 31, SLDOs are encourage to collect coats to donate to a local shelter, elder care center, veterans' center, or women's center. Collecting coats saves lives, as the health effects of extreme cold can be life threatening, ranging from heart attacks to pneumonia. In 2019, the SLDOs collected over 2,000 coats, with **Washington Defense Trial Lawyers** collecting over 1,200 coats! Which SLDO will win this year? The Golden Coat trophy will be announced and presented at the 2020 leadership meeting in Chicago. Let the collecting and race for bragging rights begin!

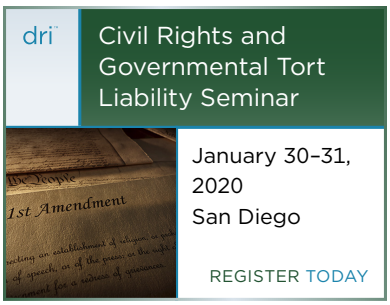
Upcoming Seminars

Women in the Law, January 22–24, 2020



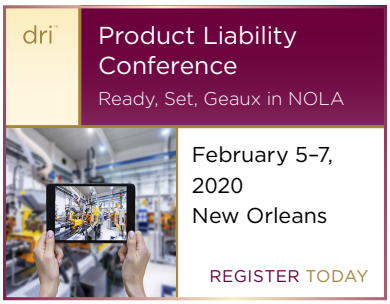
This is a seminar unlike any other. It is the best networking event for women lawyers. We gather outstanding women from law firms and corporate legal departments around the country to provide you with practical advice, excellent programming on aspects of the law that span all substantive areas, and the opportunity to build lasting relationships with the women you encounter. If you have attended this seminar in the past, you know this to be true. If you have never attended, we encourage you to join this amazing group of women as we strive to inspire and support each other. We sincerely hope that you will consider attending this year's DRI Women in the Law Seminar as we celebrate our history and look forward to our very bright future. Click here to view the brochure and to register for the program.

Civil Rights and Governmental Tort Liability, January 30–31, 2020



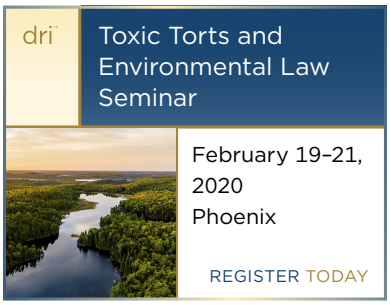
DRI's 33rd annual Civil Rights and Governmental Tort Liability Seminar will provide you with the tools to represent governmental entities from pre-claim through trial. Among this year's faculty are a renowned Supreme Court advocate, experts on municipal issues, insurance claims professionals, in-house counsel, defense attorneys, and risk management professionals. The speakers will cover trends from across the country and address timely topics relevant to your practice, including matters related to prison intake, the First Amendment, and Title IX. Attendees will also learn practical tips for addressing issues in the areas of qualified immunity, *Monell* claims, Rule 68 offers of judgment, and more. Attendees will be offered opportunities to network and exchange ideas on the topics and techniques presented with experienced litigators and claims professionals. Click here to view the brochure and to register for the program.

Product Liability, February 5–7, 2020



Join us for Products 2020 in New Orleans, a city known for food, more food, music, and fun! Once again, we will have lots of opportunities for networking in great spots throughout this wonderful city. Combined with presentations on the development and use of virtual reality, improving your PowerPoint presentations, and the usual diverse and interesting sessions from our specialized litigation groups, this is a program that you will not want to miss! Click here to view the brochure and to register for the program.

Toxic Torts and Environmental Law, February 19–21, 2020



DRI heads west with the latest in toxic torts and environmental law to keep your practice on the cutting edge. Come to Phoenix to learn about the latest updates and changes in toxic torts and environmental law with the best lawyers, judges, and experts across the country. This is the premier gathering for the defense bar, focusing on litigation strategies and regulatory updates, presented in beautiful Arizona. Click here to view the brochure and to register for the program.

Upcoming Webinars

Brace Yourself—The CCPA Is Coming, December 13, 2019, 12:00 pm–1:00 pm CST

The clock is ticking! The California Consumer Privacy Act (CCPA) has a compliance date of January 1, 2020. Yet many businesses still don't know what they need to do to comply—or worse, they don't realize that they are covered by the law. But no need to panic! This webinar will prepare both in-house and outside counsel for the inevitability of this new, broad privacy law. Given the CCPA's potential penalties for noncompliance, no one wants to stumble. Click here to register.

Preventing Amygdala Hijack at Deposition in the Reptilian Era, January 7, 2020, 12:00 pm–1:30 pm CST

The witness brain is inherently wired to defend itself in the face of an adversarial examination and unfavorable case facts. That defensive survival response, resulting from subcortical amygdala activation (amygdala "hijack"), comes in the form of forced explanations designed to defeat the questioner (fight), reframe the issue or "put lipstick on a pig" (flight), or pivot to a different issue (evade). A witness's ability to control emotion depends on having the capacity to modulate negative emotional responses through cognitive-emotional strategies, which will be covered in this program. Additionally, this program will also include the very latest updates on the plaintiff reptile revolution efforts across the country and the various defense methods being used to defeat it at every phase of litigation. Click here to register.

Quote of the Week

"If the urge to write should ever leave me, I want that day to be my last."

—Naguib Mahfouz (b. Dec. 11, 1911).