CHAPTER 16 Methodology

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Methodology

Evaluation of an expert's methodology is at the heart of *Daubert* analysis. In *Daubert*, the Court described the threshold test of admissibility as "a preliminary assessment of whether the testimony's underlying reasoning or methodology is scientifically valid and properly can be applied to the facts at issue." 509 U.S. at 592–93. The various non-exclusive "factors" often discussed in post-*Daubert* cases were offered as tools for this assessment of methodology.

As expanded by *Kumho Tire* and the Federal Rules of Evidence to the testimony of all expert witnesses, the evaluation of methodology looks at whether "the testimony is the product of reliable principles and methods" and whether the expert "has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702. This section examines cases that focus specifically on such an assessment of an expert's methodology.

These cases touch on many of the issues that arise under *Daubert* and its progeny, because the assessment of methodology employs so many of the "factors" and other considerations articulated. In particular, "general acceptance" in the relevant scientific or professional community of an expert's method of arriving at an opinion is frequently used as a gauge of reliability. And, because "conclusions and methodology are not entirely distinct from one another," 522 U.S. at 146, assessment of methodology is the main vehicle for finding an "analytical gap" between the expert's methodology and his or her conclusions as, for example, where the expert fails to conduct studies or examinations ordinarily performed.

First Circuit

United States v. 33.92356 Acres of Land 585 F.3d 1 (1st Cir. 2009)

Factual Summary

The government initiated condemnation proceedings against a landowner for a 34-acre tract of land for use as a radio beacon for aircraft navigation. The landowner disputed only the amount of just compensation. To support his valuation, the landowner offered the testimony of Carlos Gaztambide on the land's value. Mr. Gaztambide opined as to the highest and best use of the property for residential use and for sand extraction. Neither of these uses was permitted under the applicable B-2 zoning for the property without per-

mission from the Planning Board. However, Mr. Gaztambide opined that variances had been approved for both residential construction and sand extraction on "comparable land." The government challenged this testimony as unreliable, arguing, inter alia, that Mr. Gaztambide's valuation methodology made unsupported assumptions. The district court excluded this testimony, stating that he did not have a sufficient basis to conclude that zoning regulations would change or that a variance would be granted. The First Circuit affirmed, concluding that Mr. Gaztambide's opinion lacked support and made unwarranted assumptions. Accordingly, it lacked reliability and was inadmissible.

Key Language

- "The gatekeeping role of the district court is particularly pronounced in condemnation proceedings under Rule 71.1. While the jury tries issues of valuation, the trial judge must screen the proffered best and highest uses and 'exclude from jury consideration those which have not been demonstrated to be practicable and reasonably probable uses." 33.92356 Acres of Land, 585 F.3d at 8 (quoting United States v. 320.0 Acres of Land, 605 F.2d 762, 815 (5th Cir. 1979)).
- "Gaztambide had not spoken to anyone at the Board or otherwise offered any support for his opinion that the Board would approve a rezoning, variance, or permits for residential development or sand extraction on this land. Nor was there evidence that such variances had been permitted with respect to similarly zoned parcels in the past.... There was no evidence that any of the parcels that Gaztambide had relied on to show residential development were or had been zoned B-2. The expert also relied on applications to obtain permits for residential development on other parts of the 400 acres which the defendant had filed in 1999. However, these applications remained pending in 2007, and to this day there is no evidence that these permits were granted. Similarly, the expert had not reviewed or identified any document showing that sand extraction was ever permitted in land that is zoned B-2. In this case the support for the expert's opinion was sufficiently sparse that the court did not abuse its discretion in holding that the expert testimony did not meet the standards of Rule 702." Id.

Santos v. Posadas De P.R. Assocs., Inc. 452 F.3d 59 (1st Cir. 2006)

Factual Summary

Guests brought a negligence action against their hotel after slipping and falling while entering the hotel's pool. The plaintiffs alleged that the design and material used to construct the steps leading into the pool, as well as the absence of a handrail, created a "perilous condition." The hotel appealed a jury verdict in favor of Plaintiffs, challenging the district court's decision to admit the testimony of the plaintiffs' liability expert, Dr. Ricardo Galdós, that there was a dangerous condition on the hotel's premises. Specifically, the hotel attacked the expert's qualifications and his methodology. This methodology consisted of interviewing the plaintiff, visiting the hotel's pool, measuring the steps at issue, photographing the area, reviewing applicable codes and standards, making "needed calculations," and applying prior friction testing of various tiles to the tiles in the hotel's pool. The First Circuit affirmed, holding that this methodology was sufficient to permit the expert's opinion to go to the jury.

Key Language

• The First Circuit concluded that the district court's determination that the expert's approach "was scientifically plausible and that this methodology possessed adequate indicia of reliability" was "within the encincture of the trial court's discretion," citing a prior decision that concluded reviewing records, receiving a letter, and conducting interviews was sufficient methodology for a life-care planning expert. Santos, 452 F.3d at 64 (citing Marcano Rivera v. Turbado Med. Ctr. P'ship, 415 F.3d 162, 171 (1st Cir. 2005)).

Correa v. Cruisers, a Div. of KCS Int'l, Inc. 298 F.3d 13 (1st Cir. 2002)

Factual Summary

Motorboat purchasers brought breach of warranty action against boat manufacturer and manufacturer of boat's marine gasoline engines. Defendants appealed from a jury verdict finding that they breached a warranty against hidden defects in the sale of a motorboat to plaintiffs. In particular, the defendants contended that the district court erred in allowing the testimony of the plaintiff's expert, on the ground that his methodology for determining that the engines were defective was unreliable because he did not use any instruments to inspect the engines. The First Circuit affirmed, holding that a visual inspection, accompanied by removal of a spark plug, was a sufficiently reliable methodology. Expert: Ramon Echeandia (mechanical engineer, on engine inspection).

Key Language

- "Although plaintiffs did not offer any evidence that [their expert's] visual inspection of the engine was a well-accepted method of diagnosing the existence of engine or fuel management problems, here, we find it to be a matter of common sense that a visual inspection, including observation of excessive smoke and 'fouled up' spark plugs, would be one acceptable way for a mechanic or engineer to detect an engine problem." Correa, 298 F.3d at 26.
- "Acceptance of the methodology by the other party's expert may give additional credence to the reliability of the proffered testimony." Id.

Practice Tip

What is the first thing an auto mechanic usually does? Open the hood and look inside. Appropriate methodology is a function of the discipline, profession or trade in which an expert operates. With Daubert standards applicable to all experts after Kumho Tire, it is necessary to deconstruct how each discipline, profession, or trade goes about analyzing the issue at hand.

Seahorse Marine Supplies, Inc. v. P.R. Sun Oil Co. 295 F.3d 68 (1st Cir. 2002)

Factual Summary

A marine fuel distributor brought an action against a fuel refinery, alleging that the refinery improperly terminated the parties' franchise relationship in violation of the Petroleum Marketing Practices Act. The district court granted judgment for the distributor. The refinery appealed, alleging that the admission of the expert testimony regarding damages for lost profits and the value of the businesses as a going concern was an abuse of discretion, as her methodology was inherently unreliable and flawed because the methodology failed to take into account the fuel distributor's failure to pay various taxes and that her future damages calculations were purely speculative. The First Circuit affirmed. Expert: Heidie Calero (discipline not specified, testifying on damages).

- The expert's testimony regarding lost profits was properly admitted given her "plain testimony and Sun Oil's failure to meaningfully point out any discrepancy in the record.... Moreover, to the extent that Sun Oil sought to prove that [the expert's] tax calculations were flawed, it followed the proper course of action by rebutting the testimony with its own expert." Seahorse Marine Supplies, Inc., 295 F.3d at 81.
- The expert's "forecast of damages over a ten-year period, however, is more troublesome.... We need

not decide whether this time period was unduly speculative [given the jury's ultimate award even though]... the district court may have erred by allowing [the expert] to forecast for ten years." *Id.*

Babcock v. Gen. Motors Corp. 299 F.3d 60 (1st Cir. 2002)

Factual Summary

The estate of a motorist who died from injuries sustained in single-automobile crash sued the automobile manufacturer on the basis of negligence and strict liability. After a jury verdict against it, the manufacturer appealed on the grounds that the plaintiff's expert should not have been allowed to testify as to impact speed and "false latching" as the probable cause of injuries, as those opinions were based on faulty methodologies. Those methodologies included determining the rate of speed by analyzing photographs of the crash scene and determining the presence of false latching by examining the seatbelt utilized by the victim. The First Circuit affirmed, holding that the executrix' expert determined crash speed by a methodology generally accepted in the accident reconstruction field and approved by the National Highway Traffic Safety Administration (NHTSA). The First Circuit also upheld the methodology underlying the executrix's expert's opinion about the "false-latching" of the victim's seatbelt. Expert: Dr. Malcolm Newman (structural and mechanical engineer, on design defect and causation).

Key Language

• In opining on the plaintiff's expert's methodology for reaching his conclusions regarding the speeds of the vehicles involved in the accident, as well as his opinion that the victim's seatbelt had "false latched," the First Circuit stated "[i]t is apparent to us that the expert's testimony met the standards set forth in *Daubert*. The evidence admitted was both relevant and reliable." *Id.* at 67.

Ferrara & DiMercurio v. St. Paul Mercury Ins. Co. 240 F.3d 1 (1st Cir. 2001)

Factual Summary

The owner of a commercial fishing vessel brought an action against a marine insurer, alleging that the insurer's refusal to pay a claim under a hull policy for destruction of a vessel by fire was a breach of an insurance contract and constituted bad faith in violation of Massachusetts consumer protection laws. The district court granted judgment as a matter of law for the

owner on the contract claim but dismissed the bad faith claim. The First Circuit reversed and remanded for a new trial. Following a jury trial and verdict in favor of the maritime insurer, the owner appealed on the grounds that the insurer's expert opinion was impermissibly based upon a flawed methodology, namely, his reliance on the other—originally retained (and now deceased)—expert's report. The First Circuit affirmed. Expert: John Malcolm (licensed electrician, on fire cause and origin).

Key Language

- The First Circuit held that "a cause-and-origin expert like [the insurer's] could be expected to examine the report of another expert... as well as the fire department's report in the course of forming his own opinion derived from a variety of sources, including his own first hand knowledge of the primary evidence at the fire scene." Ferrara & DiMercurio, 240 F.3d. at 9.
- "This Court has said that when an expert relies on the opinion of another, such reliance goes to the weight, not the admissibility, of the expert's opinion." *Id*.

Cummings v. Standard Register Co. 265 F.3d 56 (1st Cir. 2001)

Factual Summary

Former employee sued former employer, alleging that his termination was the result of age discrimination in violation of Massachusetts law. A jury awarded \$990,000 back pay, front pay, and emotional distress damages to employee. The defendant appealed, alleging that the district court erred by admitting expert testimony based upon a flawed methodology in calculating the plaintiff's future losses. Specifically, the defendant contended that the plaintiff's expert failed to take into account company specific data, such as the average retirement age of its workers or its salary caps, and utilized an unusually high earnings year as a base point in his calculation, which ultimately contributed to an inflated and inaccurate forecast of front pay damages. The First Circuit affirmed the district court's decision to let the testimony stand. Expert: Martin Duffy (vocational economist, on damages).

- "Standard Register has failed to show how the information [the expert] did use was incorrect and does not dispute the district court's conclusion that [the expert's] assumptions are ones the economists make with some frequency." *Cummings*, 265 F.3d at 65.
- The First Circuit agreed "that whatever shortcom-

ings existed in [the expert's] calculations went to the weight, not the admissibility, of the testimony" and upheld the district court's decision to allow it. Id.

Practice Tip

This case illustrates the widespread tendency to accept vocational economics testimony uncritically because it has been used widely.

United States v. Shea 211 F.3d 658 (1st Cir. 2000)

Factual Summary

Five defendants were convicted in the district court on charges of conspiracy to commit robbery, operating a racketeering enterprise, carjacking, and firearm offenses, and four of the defendants were sentenced to life imprisonment. The defendants appealed their convictions, alleging that the admission of expert DNA testimony was an abuse of discretion by the district court, as the expert's opinion was based upon a flawed methodology. Specifically, the defendants argued that the government's expert failed to note one faint allele dot in a sample of sweat taken from a baseball cap found in a getaway vehicle, the DNA of which the government's expert had matched to one of the defendant's blood sample. The First Circuit affirmed the convictions and held that the admission of the DNA evidence was not an abuse of discretion. Expert: Dr. Harold Deadman (DNA expert).

Key Language

• "Most circuits that have agreed with this approach... relying on the view that 'cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof' is the proper challenge to 'shaky but admissible evidence." Shea, 211 F.3d at 668.

Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co. 161 F.3d 77 (1st Cir. 1998)

Factual Summary

The plaintiffs brought suit against a truck driver, his employer, and others following an accident in which an automobile collided head-on with a truck, resulting in the death of the driver and five passengers in the automobile. Following a jury verdict finding the truck driver forty-one percent responsible for the accident and awarding damages, the defendants appealed, alleging that their pharmacologist's proposed expert testimony relating to amount of drugs that the driver consumed and time of their consumption, arrived at by interpolation from toxicology results using half-life methodology, was sufficiently reliable under Daubert and should have been admitted. The First Circuit reversed and remanded for a new trial, holding that the methodology was sufficiently reliable. Expert: Dr. James O'Donnell (pharmacologist, on drug intoxication levels).

Key Language

- "[W]hile methodology remains the central focus of a *Daubert* inquiry, this focus need not completely pretermit judicial consideration of an expert's conclusions. Rather, trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable." Ruiz-Troche, 161 F.3d. at 81.
- "Although [the defendants' expert report] cites numerous scientific writings in support of the methodology underlying [his] proposition, the lower court found none of these sources adequate to imbue the proffered opinions with the patina of reliability required by Daubert." Id. at 83.
- The First Circuit held, however, "[t]he publication of these [scientific writings] and their exposure to peer review serve as independent indicia of the reliability of the half-life technique. By the same token, publication and peer review also demonstrate a measure of acceptance of the methodology within the scientific community." Id. at 84.

Practice Tip

This case illustrates the strong connection between "general acceptance" in the relevant community and assessment of methodology. If a methodology is accepted by practitioners in the field, that is evidence that the expert has followed appropriate methodology.

Nna v. Am. Standard, Inc. 630 F. Supp. 2d 115 (D. Mass. 2009)

Factual Summary

Injured transit workers, as well as the wife of a deceased transit worker, brought negligence, gross negligence, and breach of warranty claims against the manufacturer of a train horn that allegedly failed to sound prior to the train striking them as they cleared ice from the tracks. The plaintiffs claimed that the horn failed because of snow and ice accumulation inside of the horn's bell, and alleged that the manufacturer should have equipped the horn with a protective cover and/or warned of the potential dangers of its use in winter environments. The defendant moved

for summary judgment on the ground that Plaintiff had not provided any admissible evidence of causation—i.e., that the workers would have had sufficient time to avoid the collision if the horn sounded. Specifically, the defendant challenged the opinions of two of the plaintiff's experts as inadmissible. First, the opinions of Thomas Johnson, a licensed professional engineer and accident reconstructionist, as to the amount of time the workers had to move away and whether this amount was sufficient to avoid the collision. Second, it challenged the opinions of Dr. John Mroszcyk, a registered professional engineer with a Ph.D. in applied mathematics, that if the horn had been operable it would have provided an auditory warning and would have provided enough time for the workers to clear the track and avoid a collision. Although the court concluded that Johnson's opinion as to the amount of time was sufficiently reliable, it held that his opinion as to the sufficiency of that time lacked an adequate foundation and was therefore impermissible. The court further held that the opinion of Dr. Mroszcyk, which also addressed the sufficiency of time, was likewise unreliable. As a result, the court granted-in-part and deniedin-part the defendant's motion to exclude.

Key Language

- "Although the *Daubert* decision focused primarily on an expert's methodology, trial judges may also 'evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable." *Nna*, 630 F. Supp. 2d at 133 (quoting *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998)).
- With respect to Mr. Johnson's sufficiency opinion, the court stated that "[t]his conclusion appears to be based on nothing other than Johnson's general observation that '[i]t is entirely reasonable to expect that these three experienced MBTA employees would have immediately understood the urgency to move away from the path of the train upon hearing the train horn.' In the absence of any identifiable methodology, beyond Johnson's general impression of how quickly experienced railroad employees can move, his conclusion as to the sufficiency of the time to move away is not admissible as an expert opinion." *Id.* at 136–37.
- With respect to Dr. Mroszcyk's opinion, the court concluded that "[t]his assertion appears to be nothing more than a bare, unsupported conclusion, which is not saved from inadmissibility by Plaintiffs' contention that it was 'based on [Mroszczyk's]

review and understanding of the opinions of Mr. Johnson.' As discussed above, Johnson's conclusion as to the sufficiency of time for the work crew to reach a point of safety was itself inadmissible for similar reasons." *Id.* at 137.

United States ex rel. Loughren v. UnumProvident Corp. 604 F. Supp. 2d 259 (D. Mass. 2009)

Factual Summary

A whistleblower plaintiff brought a qui tam action against a corporation for alleged violations of the False Claims Act. The plaintiff alleged that the defendant insurers caused their insureds to file applications with the Social Security Administration for disability benefits that falsely claimed that they were disabled or unable to work. The group of insureds that allegedly fell into this category was over 468,000. Because of the number of alleged claims, the plaintiff, instead of examining each claim individually to determine if it was improper, relied on statistical sampling and extrapolation. To that end, the plaintiff offered the testimony of a statistical expert, Matthew Mercurio, Ph.D., to extrapolate from the number of false claims within a sample of claims to an estimation of the total number of false claims filed. Dr. Mercurio used a process of "cohort sampling," in which groups sharing a specific trait that make them more likely to possess a desired characteristic are more heavily sampled, then the result from each group is reweighted to account for that group's proportion of the overall population. To account for overlap between his chosen "cohorts," Dr. Mercurio applied a "weighted average" extrapolation technique. The defendants filed a motion to exclude, challenging Dr. Mercurio on numerous grounds, including his statistical methodology and the size of his conclusion's level of precision, which was \pm 5868.3 claims. The court granted the defendants' motion, agreeing that Dr. Mercurio's methodology, specifically his use of overlapping cohorts and his method of accounting for the overlap, as well as his level of precision, was unreliable.

Key Language

- "[T]he Court concludes that extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate." *Loughren*, 604 F. Supp. 2d at 261.
- "An expert's methodology is the 'central focus of a Daubert inquiry,' but a court 'may evaluate the data offered to support an expert's bottom-line opinions

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- to determine if that data provides adequate support to mark the expert's testimony as reliable." Id. at 264 (quoting Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 81 (1st Cir. 1998)).
- "[T]he Court is troubled by the size of the confidence interval, \pm 5,868.3 claims, in Mercurio's final calculation of 8,027 false claims, with 95 percent confidence. \pm 5,868.3 claims is an extremely wide confidence interval.... Viewed in this manner, Mercurio's result amounts only to a conclusion that somewhere between 2,158.7 and 13,895.3 false claims were filed, with 95 percent confidence. As the Reference Manual on Scientific Evidence states, 'a broad interval signals that random error is substantial'; 'the standard error measures the likely size of the random error.... If the standard error is large, the estimate may be seriously wrong.' David H. Kaye & David A. Freedman, Reference Guide on Statistics, in Reference Manual on Scientific Evidence 83, 119 n. 120, 118 (Fed. Judicial Ctr. 2d ed. 2000). This leaves the Court's confidence in the reliability of Mercurio's result shaken." Id. at 269.
- "Even were the size of the confidence interval smaller, Mercurio's flawed attempt to use weighted averages and to compensate for the overlapping nature of the cohorts renders his method unreliable. It is the plaintiff's burden to prove by a preponderance of the evidence that Mercurio's testimony is reliable, and the plaintiff has failed to establish that Mercurio's method of using weighted averages to compensate for the overlapping nature of the cohorts has been subject to peer review and publication, or has gained acceptance within the relevant discipline. More fundamentally, [the defendant] has presented convincing evidence that the technique is susceptible to manipulation and significant error." Id.

Bado-Santana v. Ford Motor Co. 482 F. Supp. 2d 192 (D. P.R. 2007)

Factual Summary

A passenger in an automobile that overturned during a crash brought a negligence claim against the manufacturer, alleging that she sustained Mild Traumatic Brain Injury ("MTBI") as a result of the crash. In support of her claims, the plaintiff offered the testimony of Dr. Maria Margarida, a neuropsychologist, who used criteria from the American Congress of Rehabilitation to determine that the plaintiff suffered a MTBI, but who did not interview the psychiatrists who were treating the plaintiff at the time of the crash. The defendant challenged this failure to interview the plaintiff's prior treating

physicians, examining their medical records, the testimony of other passengers in the vehicle, or determining if the plaintiff actually suffered a head trauma during the crash sequence as an unreliable methodology. The court denied the defendant's motion in limine to preclude this testimony at trial, concluding that these failures were fodder for cross-examination, rather than rendering Dr. Margarida's methodology unreliable.

Key Language

- "Defendant argues that this failure to consider relevant information is fatal. The court disagrees. Challenges to the methodology used by an expert witness are usually adequately addressed by crossexamination. Because defendant has not shown why that cannot be the case here, the court will not exclude Dr. Margarida's testimony for failing to interview Cortes' treating physicians and rearpassenger Israel Dominicci, as well as consider their respective accounts." Bado-Santana, 482 F. Supp. 2d at 197 (citations omitted).
- "In reviewing the reliability of Dr. Margarida's proffered expert testimony, the court's focus is on her methodologies and not on the conclusions she generated. In this case, Dr. Margarida used a theory that is widely used and which has been published and subject to peer review. Any flaws in Dr. Margarida's opinion go to the weight of the evidence, rather than to its admissibility. Therefore, the court will not exclude Dr. Margarida's testimony for allegedly using a flawed methodology." Id. (citations omitted).

Alves v. Mazda Motor of Am., Inc. 448 F. Supp. 2d 285 (D. Mass. 2006)

Factual Summary

The owner of an automobile who was injured during a low-speed crash brought negligence/defective design, failure to warn, and breach of implied warranty claims against the manufacturer, alleging that her air bags improperly deployed, rendering her blind. Defendants challenged the methodology used by the plaintiff's engineering experts in calculating the "barrier equivalent velocity" (BEV) at which the plaintiff's vehicle crashed. According to the manufacturer's brochure, the air bag should deploy in a frontal collision fourteen miles per hour or greater. The plaintiff's experts concluded that the plaintiff's crash occurred at six and nine miles per hour. To reach this conclusion, both experts used a methodology from a published article that explained how to estimate BEV based on the damage to the vehicle to calculate the speed of the crash. The court granted the defendants' motion to preclude this testimony as a discovery sanction, concluding that regardless of any discovery violation, the testimony was not admissible pursuant to *Daubert* and the Federal Rules. Specifically, the court stated that the plaintiff's experts did not apply the methodology outlined in the article reliably to the facts of the case because the article stated that the method it espoused was less accurate if the crash occurred on the edge of the study's fifteen-to-sixty mile per hour range. Since the plaintiff's experts' conclusions were that the crash was either six or nine miles per hour, the court concluded it was an unreliable applicable of a potentially reliable methodology.

Key Language

• "As Professor Salzburg has written, '[m] any experts after Daubert have fallen into the trap of relying on a proper methodology, but failing to connect it to the facts of the case."... In the instant case, Alves' experts have identified a methodology that appears to be reliable in certain circumstances, but which the sole article describing it indicates is not reliable at the speed at which she and her experts estimate her Mazda was traveling. Thus, Federal Rule of Evidence 702(2) and (3) operate to exclude the experts' evidence because the witnesses have not applied a methodology that may be reliable in certain circumstances 'reliably to the facts of the case." Alves, 448 F. Supp. 2d at 299 (citations omitted).

United States v. Monteiro 407 F. Supp. 2d 351 (D. Mass. 2006)

Factual Summary

The defendants were indicted for violations of the Racketeer Influenced and Corrupt Organizations Act (RICO) based, in part, on cartridge cases recovered from the scenes of various shootings. The defendants sought to exclude expert testimony that the cartridge cases recovered from those scenes matched the cartridge cases test-fired from guns linked to the defendants. The defendants argued, in part, that the methodology used in firearms identification was unreliable under *Daubert*. The court ruled that although the expert's methodology was reliable, the expert opinion was inadmissible because the expert failed to conform to the documentation and peer review standards of the ballistics field. Expert: Sgt. Douglas Weddleton (Massachusetts State Police firearms examiner).

Key Language

• "As pointed out above, one critical problem with the

AFTE Theory is the lack of objective standards...." *Monteiro*, 407 F. Supp. 2d at 370. "The question, then, is whether a method that relies on the individual examiner's training and experience to distinguish between characteristics on a cartridge casing is fatal to the reliability of the technique on the whole." *Id.* at 371.

 "[T]his Court holds that the underlying scientific principle behind firearm identification—that firearms transfer unique toolmarks to spent cartridge cases—is valid under *Daubert*." *Id.* at 355.

Fullerton v. Gen. Motors Corp. 408 F. Supp. 2d 51 (D. Me. 2006)

Factual Summary

The plaintiff was injured when her car allegedly slipped out of "park" and into "reverse." The defendant moved to exclude expert testimony on the basis that it did not rest upon any valid methodology. The court held that any issues with the purported expert's testimony went to weight, not admissibility. Expert: Neil Mizen (mechanical engineering).

Key Language

- "Contrary to the defendant's contention, it is not necessary that Mizen 'rely on any industry standard, scholarly publication, research or scientifically valid analysis,' to support his choice of a shorthand title for this condition." *Fullerton*, 408 F. Supp. 2d at 55.
- "...Mizen was not asked at deposition about the methodology be [sic] used in reaching this conclusion. His affidavit testimony is sufficient to overcome the defendant's argument; the defendant has not shown that an 'engineering basis' for the opinion is legally required, or indeed what an 'engineering basis' would be, as distinguished from the information Mizen has provided." *Id.* at 56.

Brown v. Wal-Mart Stores, Inc. 402 F. Supp. 2d 303 (D. Me. 2005)

Factual Summary

The plaintiff brought a personal injury claim alleging she was injured when she was hit by falling merchandise while walking down a store aisle. The plaintiff sought to introduce expert testimony that improperly stacked merchandise on freestanding shelves may fall if bumped. The court excluded the testimony on the grounds that the expert did not reveal any scientific methodology for his conclusions which "merely place an expert sheen on common sense." *Brown*, 402 F. Supp. 2d at 309. Expert: David Dodge (engineer).

Key Language

• "In sum, Mr. Dodge failed to offer an opinion even remotely helpful to a fact finder, he did not disclose any scientific methodology used to arrive at his conclusions, and even if his conclusions were based solely or primarily on personal experience, he did not explain how his 'experience le[d] to the conclusion[s] reached, why that experience [was] a sufficient basis for the opinion, and how that experience [was] reliably applied to the facts." Id. at 310.

United States v. Green 405 F. Supp. 2d 104 (D. Mass. 2005)

Factual Summary

The defendants were indicted with racketeering, assault in aid of racketeering, and various gun charges. The defendants sought to exclude the ballistics testimony of Detective O'Shea on the grounds that O'Shea was not certified by any professional organization and did not follow any established methodology in his ballistics analysis. The court admitted O'Shea's testimony—acknowledging that he did not follow any sound methodology and stating that, with the notable exception of U.S. v. Monteiro, the precedent was to admit even highly subjective ballistics testimony. Expert: James O'Shea (Boston Police Sergeant Detective).

Key Language

- "Although O'Shea has seven years of experience in the Boston Police Ballistics unit, neither he nor the laboratory in which he worked has been certified by any professional organization. He has worked on hundreds of cases, but has never been formally tested by a neutral proficiency examiner. Nor could he cite any reliable report describing his error rates, that of his laboratory, or indeed, that of the field." Green, 405 F. Supp. 2d at 107.
- "In distinguishing class and sub-class characteristics from individual ones, O'Shea did not have many resources to rely on. He conceded, over and over again, that he relied mainly on his subjective judgment. There were no reference materials of any specificity, no national or even local database on which he relied. And although he relied on his past experience with these weapons, he had no notes or pictures memorializing his past observations. He could have contacted the Hi Point manufacturer directly to ask about how the particular gun he was examining was manufactured or obtain diagrams or photographs of its features, but he did not." Id.

 "I reluctantly come to the above conclusion because of my confidence that any other decision will be rejected by appellate courts, in light of precedents across the country, regardless of the findings I have made. While I recognize that the Daubert-Kumho standard does not require the illusory perfection of a television show (CSI, this wasn't), when liberty hangs in the balance—and, in the case of the defendants facing the death penalty, life itself—the standards should be higher than were met in this case, and than have been imposed across the country. The more courts admit this type of toolmark evidence without requiring documentation, proficiency testing, or evidence of reliability, the more sloppy practices will endure; we should require more." Id. at 109.

United States v. Lowe

954 F. Supp. 401 (D. Mass. 1997)

Factual Summary

In prosecution for carjacking, kidnapping, and forcible transportation of another for sexual activity, the defendant filed a motion to exclude evidence that his DNA profile matched DNA samples in a rape kit. The district court held, as a matter of first impression, that using chemiluminescence in the detection phase of restriction fragment length polymorphism (RFLP) analysis was scientifically valid, other protocol changes by FBI for RFLP analysis had no significant impact on reliability, using polymarker and D1S80 loci in polymerase chain reaction analysis (PCR) was sufficiently reliable, using product rule was valid in PCR analysis, risk of contamination did not render results unreliable, and failure of FBI to undergo blind proficiency testing for PCR-based tests did not render results unreliable. The motions were denied. Experts: Dr. Martin L. Tracey (biologist); Alan M. Giusti (FBI forensic examiner); Dr. Dan E. Krane (assistant professor of biological sciences); all on DNA testing.

- "Based on [the] solid phalanx of state and federal case law, the 1996 [National Research Council] report and the evidence at the Daubert hearing, this Court concludes that the RFLP methodology is reliable." Lowe, 954 F. Supp. at 411.
- "Based on the favorable description by the National Research Counsel's Commission on Forensic DNA Science, the peer-reviewed studies, the expert testimony at the Daubert hearing and the lack of any scientific evidence disputing the reliability of the PCR methodology at any of the three loci, the Court finds

that the PCR methodology passes *Daubert* muster with respect to DNA profiling at the Polymarker and D1S80 loci. The relative lack of experience with the D1S80 loci testing system (as contrasted with other loci) may affect the weight of the evidence, but the government has demonstrated the methodology is reliable." *Id.* at 418.

Acosta-Mestre v. Hilton Int'l of P.R., Inc. 1997 WL 373734 (D. P.R. June 6, 1997), aff'd 156 F.3d 49 (1st Cir. 1998)

Factual Summary

The defendant filed a motion in limine to exclude the plaintiffs' expert from testifying regarding the alleged design defect of a chaise lounge chair. The district court held a hearing to determine whether the plaintiffs' proposed expert should be permitted to testify as an expert in the design of lounge chairs. The court found that the plaintiffs failed to show any evidence that their expert's methodology for testing the design of the chaise lounge chair was technically valid in the engineering field. The only test performed by the expert prior to reaching his opinion included videotaping an individual lying down on a lounge chair on a concrete floor, altering the chair's backrest and then observing the results. Based on this limited methodology, the court precluded the expert's testimony. Expert: Dr. Soderstrom (mechanical engineer, on design defect).

Key Language

• The plaintiffs' expert "testified that he had no knowledge whether his methodology to test the design of the lounge chair was (1) common in the industry or engineering community, (2) subject to peer review or publication, or (3) generally accepted in the mechanical engineering field. Even under a flexible application of *Daubert*, therefore, the Court finds that Plaintiffs have not shown through any evidence that [their expert's] methodology for testing the design of the chaise lounge chair is technically valid in the engineering field." *Acosta-Mestre*, 1997 WL 373734, at *2.

Second Circuit

United States v. Williams 506 F.3d 151 (2d Cir. 2007)

Factual Summary

The defendant, along with two co-defendants, was convicted of offenses ranging from narcotics trafficking, racketeering, and murder arising from the events sur-

rounding a triple homicide. At the crime scene, investigators collected spent bullets, cartridge casings, and bullet fragments. Michelle Kuehner, a firearms examiner with the local coroner's office, matched this ballistics evidence to a 9 mm semiautomatic pistol recovered from the defendant's apartment. Her methodology consisted of comparing various "toolmarks" from the ballistics evidence recovered from the crime scene, including caliber, number of land and groove impressions, and twist and width of these impressions, with those of bullets that she test-fired from the defendant's firearm. She also compared unique "striations" from both sets of bullets. Based on her experience and training, Kuehner concluded that there was "sufficient agreement" between the two bullets and that the defendant's weapon was therefore used during the commission of the murders. The district court rejected the defendant's challenge to this methodology as unreliable without conducting a *Daubert* hearing. On appeal, the defendant argued that the district court erred by denying him a hearing and failing to undertake a sufficient inquiry into the reliability of Kuehner's methodology. The Second Circuit rejected these arguments, concluding that a hearing was not required and that there was sufficient evidence in the record for the trial court to conclude that Kuehner's methodology was reliable.

Key Language

- "While the gatekeeping function requires the district court to ascertain the reliability of [an expert's] methodology, it does not necessarily require that a separate hearing be held in order to do so.... This is particularly true if, at the time the expert testimony is presented to the jury, a sufficient basis for allowing the testimony is on the record." Williams, 506 F.3d at 161.
- "We think that *Daubert* was satisfied here. When the district court denied a separate hearing it went through the exercise of considering the use of ballistic expert testimony in other cases. Then, before the expert's testimony was presented to the jury, the government provided an exhaustive foundation for Kuehner's expertise including: her service as a firearms examiner for approximately twelve years; her receipt of 'hands-on training' from her section supervisor; attendance at seminars on firearms identification, where firearms examiners from the United States and the international community gather to present papers on current topics within the field; publication of her writings in a peer review journal; her obvious expertise with toolmark identification; her experience examining approximately 2,800 different types of firearms; and her prior expert testi-

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mony on between 20 and 30 occasions. Under the circumstances, we are satisfied that the district court effectively fulfilled its gatekeeping function under *Daubert*. The trial court's admission of Kuehner's testimony constituted an implicit determination that there was a sufficient basis for doing so. The formality of a separate hearing was not required and we find no abuse of discretion." *Id*.

• "We do not wish this opinion to be taken as saying that any proffered ballistic expert should be routinely admitted. Daubert did make plain that Rule 702 embodies a more liberal standard of admissibility for expert opinions than did Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923).... But this shift to a more permissive approach to expert testimony did not abrogate the district court's gatekeeping function. Nor did it 'grandfather' or protect from Daubert scrutiny evidence that had previously been admitted under Frye.... Because the district court's inquiry here did not stop when the separate hearing was denied, but went on with an extensive consideration of the expert's credentials and methods, the jury could, if it chose to do so, rely on her testimony which was relevant to the issues in the case." Id. at 161-62 (internal citations omitted).

LaBarge v. Joslyn Clark Controls, Inc. 242 F. App'x 780 (2d Cir. 2007)

Factual Summary

A machine operator brought negligence and failure to warn claims against two manufacturers after he was electrocuted while repairing an axle hardening machine manufactured by Tocco, Inc. The plaintiff alleged that the machine contained a defectively designed and manufactured vacuum contactor manufactured by Joslyn Clark Controls, Inc. The district court excluded testimony from the plaintiff's expert witness as to the cause of the electrocution on the grounds that "it had not been scientifically tested and was not based on direct observation of any of the parts or how the Joslyn part was installed in the Tocco axle machine." *LaBarge*, 242 F. App'x at 782. The Second Circuit affirmed.

Key Language

• "In requiring that the expert actually test his theory, rather than that the theory be *testable*, the District Court misstated the test articulated in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993): 'Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will

be whether it can be (and has been) tested.' *Daubert*, 509 U.S. at 593. The expert stated that his theory was testable, and he described in his testimony how one would devise such a test. However, the expert's basis for his theory was grounded on photographs of the hardware in question and the literature for the Joslyn part, but not the literature or engineering diagrams for the Tocco machine or any actual vacuum contactors like the part that allegedly failed. As a result, we conclude that the District Court did not abuse its discretion in determining that the testimony was not reliable because it was not grounded on sufficient facts or data." *LaBarge*, 242 F. App'x at 782.

Gussack Realty Co. v. Xerox Corp. 224 F.3d 85 (2d Cir. 2000)

Factual Summary

The plaintiffs sued Xerox for alleged contamination of their property migrating from a Xerox photocopier refurbishing plant. The district court admitted proffered expert testimony supporting the plaintiffs' contamination theory. On appeal, the defendant argued that the district court erred by admitting this testimony. The Second Circuit disagreed, holding that experts may rely on data collected by others, and that a valid methodology need not rule out all possible contamination scenarios, but rather only needed to provide sufficient support for the particular theories the expert advanced.

Key Language

• "Xerox cites to the proposition that where an expert has entirely disregarded an alternative explanation, that expert's testimony is entitled to 'zero weight' as a matter of law. [The cited proposition] is inapposite. Plaintiffs' experts here were not trying to account for the otherwise inexplicable presence of contamination on plaintiffs' property. Instead, they provided theories describing how, in the abstract, it would be possible for contamination to flow from the Xerox site to the [plaintiffs'] property." *Xerox Corp.*, 224 F.3d at 95 (internal citation omitted).

FDIC v. Suna Assocs., Inc. 80 F.3d 681 (2d Cir. 1996)

Factual Summary

FDIC proffered testimony of a real estate valuation expert, Robert Royce, in its suit to collect a deficiency against mortgage company, its principal, and its guarantor. A district court magistrate admitted valuation testi-

mony, which was based on a novel theory that combined two more conventional approaches, direct sales comparison, and income capitalization. The district court's admission of the testimony was among the issues appealed. The Second Circuit upheld the ruling, holding that general acceptance in the scientific community is not a prerequisite to a reliable methodology, but simply one factor a court should consider. The magistrate did not abuse his discretion in finding hybrid theory, which expert had sufficiently explained, reliable. Expert: Robert Royce (a real estate appraiser, on damages).

Key Language

- The Second Circuit rejected the defendant's contention that the expert's proffered testimony "was based upon a developmental analysis unknown to appraisal literature, unique to him and on factual assumptions which were without any reasonable foundation." FDIC, 80 F.3d at 687.
- In light of abuse of discretion standard of review, the expert's methodology was sufficiently reliable where the expert "testified at several points that the valuation method he used was a hybrid of two widelyrecognized methods and was the most appropriate method for valuing the class of property at issue." *Id*.

Practice Tip

Although general acceptance of a methodology may indicate that the methodology is "scientifically valid," this case reflects the corollary under *Daubert*'s framework: expert testimony is not inadmissible simply because the methodology is not generally accepted. Counsel and the court must be prepared to examine the principles that underlie a methodology.

In re Fosamax Prods. Liab. Litig. 645 F. Supp. 2d 164 (S.D. N.Y. 2009)

Factual Summary

In multi-district products liability litigation, the plaintiffs brought actions against a drug manufacturer, alleging that they developed a condition called osteonecrosis of the jaws after taking a drug for the prevention and treatment of osteoporosis. Both parties filed motions to exclude expert testimony. The defendant's motion challenged several of plaintiff's experts, including the testimony of plaintiffs' epidemiological expert Dr. Mahyar Etiman and regulatory expert Dr. Suzanne Parisian. As to Dr. Etiman, the defendant argued, in part, that the methodology underlying his causation opinion was unreliable, as he applied a Bradford Hill analysis after reviewing case reports, case series, prevalence studies, and animal studies, but his pro-

fessional expertise was in the field of observational epidemiology. The court agreed and excluded his general causation opinion. As to Dr. Parisian, the defendant argued, in part, that her opinions as to its allegedly deficient compliance with FDA standards were based on an unreliable methodology. Specifically, the defendant argued that her methodology consisted of nothing more than a selective reading of the documents provided to her by the plaintiff's counsel. The court disagreed, stating that an expert with extensive and specialized knowledge may draw conclusions based on observations, and that Dr. Parisian used the same methodology as when she worked at the FDA (and the same methodology used by the defendant's regulatory experts). Other portions of her report, however, were inadmissible and the court refused to permit her to "merely read, selectively quote from, or 'regurgitate' the evidence." In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d at 192 (quoting *In re Preempro Prods. Liab*. Litig., 554 F. Supp. 2d 871, 880, 886 (E.D. Ark. 2008)).

- "To fulfill its gate-keeping function, the district court must 'undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand,' in order to ensure that each step in the expert's analysis is reliable. However, in accordance with the liberal admissibility standards of the Federal Rules of Evidence, only serious flaws in reasoning or methodology will warrant exclusion." *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d at 173 (quoting *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002)) (internal citation omitted).
- "The strength of an expert's qualifications provides circumstantial evidence of reliability.... '[T]he more qualified the expert, the more likely that expert is using reliable methods in a reliable manner—highly qualified and respected experts don't get to be so by using unreliable methods or conducting research in an unreliable manner." *Id.* at 179 (quoting *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 616 (S.D. N.Y. 2007)).
- "Several courts that have considered the question have held that it is not proper methodology for an epidemiologist to apply the Bradford Hill factors without data from controlled studies showing an association." *Id.* at 188.
- "[E]very indication is that Dr. Etminan applies in his own work a more rigorous methodology before making causal determinations than he has in forming his

- opinions in this case. Therefore, testimony from him on general causation is excluded." Id. (internal footnote omitted).
- "Other statements by Dr. Etminan suggested a lack of expertise with the methodology he was applying.... The real issue though is the fact that Dr. Etminan seems to demand a higher level of epidemiological proof before making causal determinations in his professional work than he has in this case." Id. at 188 n.14.
- "The Court further finds that Dr. Parisian has followed an appropriate methodology. An expert is permitted to draw a conclusion from a set of observations based on extensive and specialized experience. Here, Dr. Parisian has drawn conclusions about Merck's conduct based on her review of pertinent portions of the regulatory filings for Fosamax and Merck's internal company documents. This is the methodology she applied as a Medical Officer, and Merck's regulatory experts have followed the same methodology to prepare their reports." Id. at 190-91 (internal citations omitted).

Innis Arden Golf Club v. Pitney Bowes, Inc. 629 F. Supp. 2d 175 (D. Conn. 2009)

Factual Summary

A golf club brought an action against the owners of adjoining properties claiming that they contaminated the club's land with pollutants known as polychlorinated biphenyls ("PCBs"). The club sought to recover its remediation costs pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), as well as through state law claims. To support these claims, the club offered the testimony of two experts, Dr. Swiatoslav Kaczmar and Dr. Joseph Pignatello, who opined as to the likely source of the PCB pollutants. The methodology underlying both experts' opinions was essentially the same—they examined the chemical composition of the PCBs, the topography of the property, and laboratory reports and chromatograms of soil samples. The adjoining landowners challenged this testimony as unreliable. The court excluded the testimony of both experts because they failed to account for alternative explanations and their opinions could not be tested or verified, in part, because of the golf club's conduct pre-suit and during discovery.

Key Language

• "[A]s the Supreme Court noted in Daubert, a 'key question' to be resolved in determining whether expert testimony is sufficiently reliable is whether the expert's methods are testable and falsifiable. In some

- design-defect cases, for example, courts reject expert testimony based on proposed theories that have not been tested. More generally, '[t]he hallmark of this reliability prong is the scientific method, i.e., the generation of testable hypotheses that are then subjected to the real world crucible of experimentation, falsification/validation, and replication." Innis Arden Golf Club, 629 F. Supp. 2d at 188–89 (quoting Caraker v. Sandoz Pharms. Corp., 188 F. Supp. 2d 1026, 1030 (S.D. Ill. 2001)) (internal citations omitted).
- "...Innis Arden's burden is to link the PCBs on Pitney Bowes's property to the costs Innis Arden incurred in cleaning up the PCBs on its own property. Kaczmar's testimony does not reliably make this causal connection because he failed to confront, even in passing, the possibility that PCBs released from some other property caused Innis Arden's remediation costs.... Having accounted for no other explanations other than the one he ultimately 'proved,' Kaczmar's methodology is not reliable." Id. at 189.
- The court concluded that Kaczmar's testimony was also flawed because "[a]s Kaczmar revealed in his deposition, there is no way for the Defendants or the Court to know exactly how he reached his conclusions, and even if he had more fully explained his methodology, his results could not be replicated or verified because the underlying data is not available." Id. at 190.
- "All of the concerns applicable to Kaczmar's methodology apply as well to Pignatello's... Moreover, Pignatello's approach was even more clearly flawed in one respect: he testified, supported by his engagement letter, that he was retained for the sole purpose of linking the PCB contamination to Pitney Bowes. An inquiry with a preordained conclusion is neither scientific nor legally reliable." Id.
- "At bottom, the experts' conclusions—by the experts' own admissions—were not the product of an openminded search for the truth about the Innis Arden contamination. A scientific inquiry is one based on a 'systematic pursuit' of knowledge through 'testing and confirmation.' Webster's Third New International Dictionary 2033 (Merriam-Webster 1993); see also Daubert, 509 U.S. at 593 (offering various definitions of the scientific method). Kaczmar's opinions, being based on a process that was artificially narrow and confined to an incomplete set of data, are not scientifically valid. Pignatello's findings, which are essentially duplicative of Kaczmar's, fare no better." Id.

In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.

593 F. Supp. 2d 549 (S.D. N.Y. 2008)

Factual Summary

In multi-district proceedings, public water companies sued several oil companies claiming that their water was contaminated with methyl tertiary butyl ether ("MTBE"), a gasoline additive. Contaminated water is rendered undrinkable because it has a taste and odor similar to turpentine. The plaintiffs sought to offer the testimony of Dr. William S. Cain at trial. Dr. Cain's testimony pertained to the level of MTBE in water at which consumers could perceive a taste or odor. In his opinion, consumers could detect MTBE at levels below one part per billion. To reach this conclusion, Dr. Cain took two steps. Initially, he selected one study, the "Stocking Study," out of the dozens that had been performed on which to focus. Then, he outlined potential flaws in this study (which reached a different conclusion than his own) and applied "correction factors" to lower the threshold at which consumers could detect MTBE. The defendants filed a motion in limine to exclude Dr. Cain's testimony, arguing that this methodology was unreliable. The court agreed.

Key Language

- "There are a number of problems with dividing the results of the Stocking Study by five to determine the 'true' threshold for detecting MTBE but the most fundamental one is that it lacks scientific rigor. To begin, transferring the results from a study of one substance to another has no validity.... Most importantly, Dr. Cain cannot name another scientist who has ever employed, much less approved of, such a method (i.e., dividing the results of one study by five because another study on an unrelated chemical showed that the subjects' threshold decreased by 'almost a factor of five' with repeated testing). Nor has Dr. Cain attempted to report this method in any peer-reviewed journal or 'in some public way' so that other scientists could offer criticisms or suggestions. Indeed, Dr. Cain has never used it in his day-to-day work, or applied it to any study other than the Stocking Study, which only occurred after he was hired by the plaintiffs as their expert." In re MTBE Prods. Liab. Litig., 593 F. Supp. 2d at 561 (internal footnotes omitted).
- "At most, Dr. Cain is offering an insightful hunch about what would happen had the Stocking Study been designed differently based on his research on a chemical that is unrelated to MTBE. Yet it is well established that an 'insightful, even an inspired,

- hunch' must be excluded if it 'lacks scientific rigor.'' *Id.* at 562 (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996)).
- "[W]hen an expert is offering testimony that is presented as a *scientific* conclusion and the expert's method fails to satisfy any of the factors identified in Daubert, a court should pause and take a hard look before allowing a jury to consider it. Courts are not naive about the fact that some attorneys will incorrectly instruct experts that their 'first and most important role is to be an advocate for the party who calls him as a witness.' An expert's first and most important duty is to testify truthfully and accurately to the best of his ability and leave the advocacy to the lawyers. But because some experts are misled by their attorneys, or even just mistaken, about their role in litigation, courts must continue to act as a gatekeeper in determining whether to admit the testimony." Id. at 564 (quoting Robert J. Shaughnessy, Dirty Little Secrets of Expert Testimony, Litigation, Winter 2007, at 47) (internal footnote omitted).

Cayuga Indian Nation of N.Y. v. Pataki 83 F. Supp. 2d 318 (N.D. N.Y. 2000)

Factual Summary

An Indian tribe brought action against the state to recover ancestral lands. The tribe proffered a real estate valuation expert, John Havemeyer III, who attempted to establish an appraisal figure based on calculating the appreciation of price-per-acre figures over a 204-year period. The court ruled Havemeyer's opinions inadmissible, finding his appraisal methodology contained numerous discrepancies and departed from recognized appraisal procedures—most notably his sales comparison formula that was based, in part, on apparently arbitrary "representative sales" from each of the 204 years in question. The court concluded Havemeyer's proffered testimony was so problematic that it failed the relevance test as well. Expert: John Havemeyer III (appraiser, on damages).

- "[I]t is questionable whether Havemeyer and his assistants complied with 'established appraisal practices' in collecting and selecting the sales data upon which Havemeyer ultimately relied upon in reaching his conclusions." *Pataki*, 83 F. Supp. 2d at 323.
- "The foregoing examples are only illustrations of deficiencies in Havemeyer's data. By no means, though, does this brief discussion catalog all of the reporting inaccuracies which appear to have

- occurred in Havemeyer's appraisal process. These inaccuracies, especially when taken together, seriously call into question the factual underpinnings of his appraisal." *Id.* at 325.
- The court held that the expert's opinions lacked relevance because "[p]rimarily for the reasons discussed in the preceding section [regarding the proffered testimony's reliability, the court finds that Havemeyer's testimony will not be helpful to the jury in understanding or determining how the subject property should be valued." Id. at 327.

Celebrity Cruises Inc. v. Essef Corp. 434 F. Supp. 2d 169 (S.D. N.Y. 2006)

Factual Summary

Celebrity, comprised of two companies, operated cruise liners. A water filter in the whirlpool spa on one of Celebrity's cruise ships failed, causing an outbreak of Legionnaires' disease on the ship. After sickened passengers received verdicts against both Celebrity and Essef, the designer, manufacturer, and supplier of the water filter, Celebrity brought an indemnification action against Essef, seeking the amounts it paid to the passengers, as well as damages for lost profits and lost enterprise value resulting from the outbreak. Each party filed motions to exclude the other's damages experts. The court granted-in-part and denied-in-part these motions, concluding that much of the proffered expert testimony on lost profits and lost enterprise value relied on improper, speculative, and unreliable methodologies.

Key Language

- "A minor flaw in an expert's reasoning or a slight modification of an otherwise reliable method will not render an expert's opinion per se inadmissible." Celebrity Cruises Inc., 434 F. Supp. 2d at 176 (quoting Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 267 (2d Cir. 2002)).
- "[I]t would be wrong to conclude that there is a categorical requirement that any valuation analysis must be supported by [discounted cash flow] calculations. Courts recognize that different methods may be acceptable, depending upon the context. Any analysis will be only as good as the inputs to the model. Thus, '[t]he [DCF] method involves projections of future cash flows (which are largely dependent on judgments and assumptions about a company's growth rate) and judgments about liquidity and the cost of capital.' Likewise the comparable companies method is reliable only to the extent that the companies chosen are truly comparable." Id. at 179 (quot-

- ing Peltz v. Hatten, 279 B.R. 710, 738 (D. Del. 2002)) (internal citations omitted).
- "The need for conducting a DCF analysis as a check on other methods is not as critical in instances where the initial analysis is more trustworthy. Here, however, there are flaws that doom [the expert's] analysis independent of his decision not to perform a DCF calculation. Foremost among these is the failure to justify the purported relation between the performance of the proxies and that which would have been expected for Celebrity." Id. at 180.
- "A methodology so sensitive to one highly subjective variable lacks the necessary reliability." Id. at 186.
- "Since none of the individual components of [the expert's] analysis is reliable, the average is likewise flawed, and his expert opinion will not be admitted." Id. at 187.
- While the court determined that one of Essef's experts used a methodology that "might be suspect if viewed independently," it concluded that "it is acceptable in the context of a critique of [an opposing party's expert's] opinion." *Id.* at 192.

Ellis v. Appleton Papers, Inc. 2006 WL 346417 (N.D. N.Y. 2006)

Factual Summary

Employees of Tompkins Department of Social Services (DSS) brought a personal injury claim after allegedly sustaining injuries from the carbonless copy paper (CCP) used in their office. The plaintiffs claimed that the CCP contained toxic chemicals including, but not limited to, formaldehyde, toluene diisocyanate and triisopropylbiphenols, and that the defendants knew or should have known that the CCP contained these substances. According to the plaintiffs, these chemicals caused them to develop multiple chemical sensitivities (MCS), chemical encephalopathy, toxic encephalopathy, immune disregulation and building related illness. The court excluded the testimony of both experts, Dr. Kilburn and Dr. Thrasher, because their testimony was not based on reliable, tested scientific principles or methods. Experts: Dr. Kaye Kilburn (internist); Jack. D. Thrasher, Ph.D. (toxicology/immunotoxicology).

Key Language

• "[L]ack of epidemiological support is not necessarily fatal to a proffer of expert testimony, and that reliability may be established in a number of ways... Here, not only are there no scientific test or controlled studies demonstrating a causal link between CCP and building-related illness, there is no evidence whatsoever demonstrating such a link." *Ellis*, 2006 WL 346417, at *9.

United States v. Paracha 2006 WL 12768 (S.D. N.Y. Jan. 3, 2006)

Factual Summary

The defendant was indicted on charges including conspiracy, and providing material support and resources to al Qaeda. The government sought to introduce the testimony of the defendant's proffered expert testimony on the origins, leadership and operations of al Qaeda. The defendant argued that his expert's methodology was unreliable and amounted to a biased hand-picking of sources to support a preconceived theory. The court deemed Mr. Kohlman's methodology reliable. Expert: Evan Kohlman (terrorism expert).

Key Language

- "As Kohlmann explained, his methodology consists of gathering multiple sources of information, including original and secondary sources, cross-checking and juxtaposing new information against existing information and evaluating new information to determine whether his conclusions remain consonant with the most reliable sources... His methodology is similar to that employed by his peers in his field; indeed, he explained that he works collaboratively with his peers, gathering additional information and seeking out and receiving comments on his own work." *Paracha*, 2006 WL 12768, at *20.
- "Although Kohlmann's methodology is not readily subject to testing and permits of no ready calculation of a concrete error rate, it is more reliable than a simple cherry-picking of information from websites and other sources. The testimony and evidence at the hearing demonstrate that Kohlmann's opinions and conclusions are subjected to various forms of peer review and that the opinions he proposes to offer here regarding al Qaeda's origins, leaders and certain tradecraft are generally accepted within the relevant community." *Id.*

Royal Ins. Co. of Am. v. Joseph Daniel Constr., Inc. 208 F. Supp. 2d 423 (S.D. N.Y. 2002)

Factual Summary

An insurance company sought subrogation for monies paid on a fire claim. The defendant, whose workers allegedly caused the fire, moved to preclude expert testimony of consultant Patrick J. McGinely concerning fire origin and cause, arguing that, under his own

methodology, McGinely could not conclusively demonstrate the fire's cause. The court disagreed, determining that McGinely's adherence to the investigatory protocol published by the National Fire Protection Association rendered his proffered testimony sufficiently reliable as well as relevant, and that any flaws in the credibility of his analysis would go to weight, not admissibility. Expert: Patrick J. McGinely (fire investigator, on causation).

Key Language

- "McGinely's testimony was based on his investigation of the fire, an investigation which was conducted in accordance with the professional standards and scientific methodology used by experts in fire and explosion investigations." *Royal Ins. Co. of Am.*, 208 F. Supp. 2d at 426.
- "[I]n developing his hypothesis, McGinely relied on deductive reasoning, a method recognized as 'scientific,' and identified all of the potential ignition scenarios.... After examining all of the evidence, McGinely concluded that [defendant's workers'] molten slag was 'most probably' (although not conclusively) the cause of the fire." *Id.* at 427.

Practice Tip

Outside the realm of scientific evidence and methods, evidence of "general acceptance" and valid methodology can be found in standards of associations and other bodies in the relevant field.

Lourde v. Gladstone

190 F. Supp. 2d 708 (D. Vt. 2002)

Factual Summary

The plaintiffs, a New Hampshire farmer and his family, brought numerous charges against the owner of an upwind farm in Vermont and herbicide company for alleged contamination of the plaintiff's property (land and livestock) and personal injuries. The defendants sought to exclude the plaintiffs' toxicology expert, Dr. Robert Simon, who was to testify that chemicals released by the defendant farmer contributed to ailments of the plaintiff. While both parties agreed that differential diagnosis was a valid and appropriate methodology for determining causation, the defendants claimed the differential diagnosis Dr. Simon made was unsound. The court agreed with the defendant, finding the expert failed to sufficiently consider and rule out factors related to the plaintiff's extensive previous medical history. Expert: Dr. Robert Simon (toxicologist, on causation and source).

Key Language

- The court found insufficiently reliable the expert's opinion regarding "temporal relation of exposure to illness," namely, that the symptoms experienced by plaintiffs and their livestock within three weeks of the suspect chemicals being sprayed "is irrefutable proof that the incident chemicals used by [defendant farmer], drifting in an uncontrolled manner onto the [plaintiffs'] properties, were the proximate causes of [their] animal and human adverse health symptoms and problems." *Lourde*, 190 F. Supp. 2d at 716.
- "In the end, without reliable, admissible medical doctors' opinions, or even rough estimates on levels of exposure, Dr. Simon's opinion stands mostly on the temporal relationship between alleged exposure and the onset of the reported symptoms." *Id.* at 723 n.11.

Wills v. Amerada Hess Corp. 2002 WL 140542 (S.D. N.Y. Jan. 31, 2002)

Factual Summary

The plaintiff sued on behalf of her deceased husband for wrongful death allegedly caused by toxic exposure occurring while he worked on a cargo ship owned by the defendant. The plaintiff's toxicology expert, Dr. Jesse Bidanset, submitted two reports that linked decedent's squamous cell (lymph-node related) cancer to his frequent workplace exposure to defendant's petroleum products. Court granted defendant's motion in limine to exclude Dr. Bidanset because his reports, inter alia, failed to exclude decedent's heavy smoking and regular alcohol use as factors causing his cancer, relied on data from laboratory animal rather than human studies, and did not quantify sufficiently decedent's exposure to suspect carcinogens, instead relying on evidence that exposure levels on decedent's ship were documented to have exceeded OSHA permissible exposure limits on various occasions. The court also found Dr. Bidanset's self-described "controversial" oncogene theory of causation failed each of the Daubert factors for scientific reliability. The court added that the expert's first report, a four-page opinion that named decedent's workplace exposure as the cause of his cancer, suggested that the expert made his conclusion before fully examining the medical evidence and scientific data. Expert: Dr. Jesse Bidanset (toxicologist, on causation).

Key Language

• "Plaintiff's expert is using a controversial theory ["no threshold" oncogene theory] that some toxins do not follow the dose-response relationship, but that any

- amount of exposure causes cancer." *Wills*, 2002 WL 140542, at *15.
- "Dr. Bidanset's theory would lead to an impossible link of causation. If one exposure is sufficient for causation, there would be no way to determine which exposure caused a particular cancer since we are exposed to carcinogens to some degree in the ambient environment on a daily basis." *Id.*
- "The paucity of support for his opinion in his First Report demonstrates that Dr. Bidanset was ready to form a conclusion first, without any basis, and then try to justify it." *Id.* at *10.

Coleman v. Dydula 139 F. Supp. 2d 388 (W.D. N.Y. 2001)

Factual Summary

The plaintiff alleged that the defendants caused her injuries in an automobile crash. Proffered testimony of the plaintiff's expert, Dr. Ronald Reiber, included quantifying the plaintiff's lost future wages and future health care costs. The defendants objected to wage and health care cost testimony, arguing that Reiber's projected growth rate methodology, calculated on a derivative of the U.S. Consumer Price Index, had not been sufficiently tested or peer reviewed, making it unreliable. The court disagreed and ruled that a correlation between inflation (as measured by the CPI) and wage and health care rates was a generally accepted theory among forensic economists and that that general acceptance outweighed any deficiencies in the areas of testing or peer review. Expert: Dr. Ronald Reiber (forensic economist, on damages).

- "[D]efendants cite Kumho Tire for the broad proposition that trial courts should afford very little weight to Daubert's 'general acceptance' factor when determining the reliability of testimony. By arguing in this way, defendants misread Kumho Tire. In that case, the Court only cautioned courts not to give any one of Daubert's factors undue weight. As an extreme example of what not to do, the Court related that the 'general acceptance' factor would mean little if the expert's relevant community was, for example, the field of astrology or magic. Suffice it to say, the discipline of forensic economics is a far cry from astrology, magic, or other dubious fields of 'study.' Thus, it is quite relevant that forensic economists generally recognize the validity of Reiber's methods and techniques." Coleman, 139 F. Supp. 2d at 394.
- The court disagreed with defendants' proposition

"that it is not enough for Reiber to defend his methodologies by claiming that they are well accepted in the field of forensic economics and that all of his techniques derive from 'standard, fundamental, rudimentary, run-of-the-mill' economic and mathematical principles." *Id.* While stating that no one factor is the *sine qua non* of *Daubert* analysis, the court was satisfied that Reiber's testimony "is based on established economic theory and a traceable analysis of fact." *Id.* at 397.

Practice Tip

A rare instance of a critical examination of vocational economics, looking beyond the use of simple calculations and statistics.

Prohaska v. Sofamor, S.N.C. 138 F. Supp. 2d 422 (W.D. N.Y. 2001)

Factual Summary

The plaintiff sued a maker of medical devices for allegedly defective rods and screws implanted in her spine to correct scoliosis. Because the plaintiff's medical expert, Dr. Donald Austin, failed to conduct a physical examination of the plaintiff and because his differential diagnosis lacked sufficient intellectual rigor to counteract his failure to examine the plaintiff, the court found his proffered testimony unreliable. The court also found the expert's link between the implanting of the device and the onset of plaintiff's increased pain, by itself, did not satisfy methodology criteria. A second expert, Dr. Harold Alexander, was also disqualified, in part, for relying on the first expert's discredited pain theory. Experts: Drs. Donald Austin and Harold Alexander (physicians, on diagnosis and causation).

Key Language

- "In forming his opinion, Dr. Austin did not employ the methodology he regularly used to assess the condition of his own patients. That gap, as other courts have found, is a negative admissibility factor and leaves the impression that he conducted a superficial analysis and not an extensive, first-hand review that would provide a reliable basis for the expert's conclusions." *Prohaska*, 138 F. Supp. 2d at 438 (internal citation omitted).
- "Dr. Austin relied on [plaintiff's] subjective complaints of pain as the basis for his statement that her back and leg pain was worse at the time of deposition than it was prior to the... operation. Courts have noted that simply because pain appeared to increase after implantation does not offer proof that

- the device caused the pain." *Id.* at 441 (internal citations omitted).
- "Interestingly, Dr. Alexander relies on the report of Dr. Austin.... [That] reliance on Dr. Austin allows him to note that '[plaintiff] suffered broken screws in her spinal instrumentation that contributed to her pain and disability....' However, the basis for that remark has been found to be questionable at best, as discussed above. The fact that both experts repeat it underscores the superficial analysis they each have provided based on a review of some records and each others' report." *Id.* at 442–43 (internal citations omitted).

Colon v. BIC USA, Inc. 199 F. Supp. 2d 53 (S.D. N.Y. 2001)

Factual Summary

A mother and her minor child brought suit against the defendant for severe burns the child suffered after playing with a disposable cigarette lighter. The defendant moved to exclude as unreliable the proffered testimony of expert John Nelson, who alleged that the defendant's failure to use a safer and feasible child protection device on its J-15 lighter rendered the lighter unreasonably dangerous, and that the small size and bright, attractive colors of the lighter constituted a defect. The court agreed that, because Nelson failed to develop or test any prototypes demonstrating his alternative designs, his methodology failed the testing and general acceptance prongs of a *Daubert* analysis and was unreliable. Expert: John Nelson (mechanical engineer, on product defect).

- "Adherence to engineering standards of intellectual rigor almost always requires testing of a hypothesis if the expert cannot point to an existing design in the marketplace. The presence of this factor in a design defect case also ensures that the focus of the jury's deliberation is on whether the manufacturer could have designed a safer product, not on whether an expert's proposed but untested hypothesis might bear fruit." *Colon*, 199 F. Supp. 2d at 76–77 (internal citations omitted).
- "The Court is of course mindful that 'vigorous crossexamination, presentation of contrary evidence, and careful instruction on the burden of proof [is still] the traditional and appropriate means of attacking shaky but admissible evidence.' However, cross examination of Nelson as to his methodology in this case, which consists of reviewing and revising BIC's patents while conjecturing that his revisions pres-

ent feasible and safer alternatives to the current J-15 lighter, would only be a test of his credibility, not of the reliability of his methodology—which is a matter of law to be decided by the court." *Id.* at 78 (quoting *Daubert*, 509 U.S. at 596).

Troublé v. The Wet Seal, Inc. 179 F. Supp. 2d 291 (S.D. N.Y. 2001)

Factual Summary

In a trademark infringement and dilution case brought by the seller of ready-to-wear clothes, the defendant challenged as unreliable the proffered testimony of plaintiff's expert, Marvin Traub, a former executive in the retail industry, who was to testify on the issues of customer confusion, the plaintiff's expansion strategy, and the plaintiff's damages. The court found this expert's testimony on customer confusion not reliable because, instead of conducting a broad representative sampling of retail practices, his methodology included merely visiting a limited number of stores, comparing those stores' products, and reviewing the plaintiff's logs documenting specific incidents of confusion. The expert's damages opinion similarly was excluded because it was based on a budget analysis of the stores in a single shopping mall. The court deemed the proffered opinion on the plaintiff's expansion strategy admissible, however, as the expert's analysis of documents detailing such expansion and his retailing experience were sufficiently reliable and relevant, even if essentially factual testimony. Expert: Marvin Traub (former retail executive, on customer confusion).

Key Language

- "Comparing products and store appearances is something the average trier of fact can perform without the assistance of a former retailing executive. Similarly, a trier of fact can assess customer statements evidencing confusion..." *Troublé*, 179 F. Supp. 2d at 303.
- Defendant "contends that Traub's statement and the use of these documents was an improper attempt to provide fact testimony through an expert. However, there is nothing to prevent a party's expert from making an assumption to conduct an analysis, subject to... *Daubert* and subsequent case law." *Id*.

Travelers Prop. & Cas. Corp. v. GE 150 F. Supp. 2d 360 (D. Conn. 2001)

Factual Summary

Insurer-subrogee brought a products liability action

against the manufacturer of a clothes dryer alleging that defect caused damages in at least twenty-three incidents of dryer fires. Defendant moved to exclude as unreliable the proffered opinion of John Machnicki, plaintiff's Laboratory Director, who asserted the design of dryer permitted undetectable accumulation of lint that could be ignited by the dryer's heating mechanism. The defendant also sought sanctions for Machnicki's alleged failure to fully articulate his methodology before the Daubert hearing, including during twelve days of deposition by the defendant. The court deemed Machnicki's proffered testimony reliable and relevant. Specifically, the court found that Machnicki's analysis was capable of being tested, and thus refutable by the defendant, and that his opinions were consistent with the authoritative National Fire Protection Association's investigatory guidelines. Expert: John Machnicki (Travelers' Laboratory Director, whose proffered testimony concerned product defect).

Key Language

- "Although GE has a great deal of material for cross-examination, the court finds that Machnicki's proffered testimony is the product of reliable principles and methods. Machnicki's experience, knowledge and training, taken together with the process he described during the [Daubert] hearing of analyzing the burn patterns in each dryer and then ruling out potential alternative explanations, is sufficient.... Importantly, although Machnicki did not test his theory experimentally, his theory is capable of being tested, so that GE's experts could employ testing to undercut it and, indeed, have engaged in such efforts." GE, 150 F. Supp. 2d at 366.
- "In short, Machnicki's testimony at the *Daubert* hearing convinced the court that he did follow the scientific method and a reliable methodology, but, for whatever reason, did an exceptionally poor job articulating that methodology in either his expert report or his deposition testimony." *Id.*

Freitas v. Michelin Tire Corp. 2000 WL 424187 (D. Conn. Mar. 2, 2000)

Factual Summary

The administrator of a decedent's estate sued a tire manufacturer after the decedent was killed while trying to inflate one of the defendant's tires on a wheel that was not the right size for the tire. The defendant challenged the reliability of the proffered design defect testimony of the plaintiff's expert, Dennis Carlson (the same expert whose testimony was at issue in

the Supreme Court's Kumho Tire decision). In finding Carlson's testimony concerning dangerousness of the tire and safer feasible alternative designs reliable, the court ruled that Carlson based his opinions on data reasonably relied upon by other design defect experts, and that any weaknesses in his methodology, such as an alleged shortage of textual authority in support of his opinions, would best be left for cross-examination. The court, however, agreed with the defendant that a second expert's testimony was unreliable, finding that Dr. Kenneth Laughery's proffered opinions regarding defendant's allegedly insufficient hazard warnings were inadequately supported. Specifically, Laughery admitted that he had never conducted studies that measured the noticeability of tire warnings among similarly situated consumers, only among study participants, like service station employees, who more readily recognized the fact of a tire mismatch. Experts: Dr. Dennis Carlson, Jr. (mechanical engineer); Dr. Kenneth R. Laughery (behavioral scientist, whose proffered testimony concerned product defects).

Key Language

- The court found opinion on tire design defect reliable where "mathematical calculations [were] based on a four-part test in which [expert]: (1) determine[d] the theoretical bundle strength; (2) calculate[d] the theoretical burst pressure; (3) compare[d] the theoretical burst pressures to standard calculations for bead efficiency; and (4) perform[ed] a safety factor calculation." *Freitas*, 2000 WL 424187, at *2 n.3.
- "'Trial judges must exercise sound discretion as gate-keepers of expert testimony under *Daubert*. [The defendant], however, would elevate them to the role of St. Peter at the gates of heaven, performing a searching inquiry into the depth of an expert witness's soul—separating the saved from the damned. Such an inquiry would inexorably lead to evaluating witness credibility and weight of evidence, the ageless role of the jury." *Id.* (quoting *McCullock v. H.B. Fuller Co.*, 61 F.3d 1045, 1046 (2d Cir. 1995)).
- "Dr. Laughery's inability to opine reliably concerning the noticeability of on-sidewall warnings is not cured by the plaintiff's proposed evidence concerning [decedent's] habit of reading tire sidewalls for warning information. Such anecdotal evidence is irrelevant to Dr. Laughery's scientific conclusions concerning the public at large necessary in order for his opinion to pass muster under *Daubert*." *Id.* at *5 n.10.

Jarvis v. Ford Motor Co. 1999 WL 461813 (S.D. N.Y. July 6, 1999)

Factual Summary

In a products liability action, the plaintiff claimed that a design defect in an automobile manufacturer's cruise control system caused the vehicle she was operating to accelerate suddenly, leading to a crash. The plaintiff's design defect expert, Samuel Sero, set forth three theories demonstrating the manner in which the acceleration occurred. The court deemed one of these theories unreliable because, unlike the other two, Sero had failed to replicate the theorized cruise control malfunction in a model vehicle. In ruling Sero's other two opinions admissible, the court agreed with the plaintiff that Sero's analyses were the first to "crack[] the code" in the pertinent research area by applying accepted engineering principles to create a so-called failure mode analysis. Because, the court concluded, Sero's theories were built on a sound engineering foundation, the absence of peer review or general acceptance in the scientific community did not render his methodology unreliable. The court further found that defendant's objections to the alleged rates of error in Sero's calculations merely questioned the likelihood of a particular condition occurring and were thus best addressed on cross-examination. In addition, the court determined that corroborating internal manufacturer and government documents provided Sero's two theories additional indicia of reliability. Expert: Samuel Sero (mechanical engineer, on product defect).

Key Language

- "Sero fails to demonstrate, however, how his testing of [the non-replicated] condition... accurately reflects the effect of injected signals in an actual automobile. He has not demonstrated that the frequencies, voltage, and current levels he injected into the cruise control module are commensurate to those that can be created in an actual automobile." *Jarvis*, 1999 WL 461813, at *5.
- "Defendant's dispute with Sero's first and second findings lies not in their possibility, but in the likelihood that such conditions will occur in the 'real world.' Disputes over the conclusions that can be drawn from the results of Sero's modeling analysis is properly the province of the jury." *Id.* at *7 (internal citation omitted).
- "[D]ocuments indicate that, at the very least, Ford believed that a cruise control problem could cause a sudden acceleration event, and thus lend support to Sero's finding." *Id*.

Zwillinger v. Garfield Slope Hous. Corp. 1998 WL 623589 (E.D. N.Y. Aug. 17, 1998)

Factual Summary

The plaintiff sued a building management company, carpet manufacturer and installer, and others for illnesses she allegedly suffered after a carpet was installed in her building. The plaintiff's expert, Dr. Michael Gray, wrote three opinion letters that concluded that a skin condition, blurred vision, dizziness and other ailments experienced by the plaintiff were caused by a chemical released during the carpet installation. The court found Gray's methodology unreliable because, inter alia, his theory of causation had not been tested, he was able only to name three nearly decade-old articles that supported his theory, and his less-than-rigorous methodology did not enjoy general acceptance in the scientific community. (Besides being unreliable, the court also found that Gray's opinions lacked relevance.) Expert: Dr. Michael Gray (occupational physician, on causation).

Key Language

- "[O]f greatest import to the admissibility of Dr. Gray's testimony in this case, none of these studies even attempts to test the hypothesis that exposure to gasses emitted by carpeting can alter one's immune system and render an individual 'chemically sensitive' to a wide variety of other substances." Zwillinger, 1998 WL 623589, at *14.
- "Before admitting expert testimony, a trial court must find not only that it is reliable, but also that it is 'sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.' In this case, even if Dr. Gray could reliably testify that, as a general matter, exposure to certain chemicals may activate the immune system and render an individual 'chemically sensitive' to a broad range of substances, his deposition testimony demonstrates that he would be unable to tie that conclusion to the facts presented by this case." *Id.* at *18 (internal citation omitted).
- "While no one *Daubert* factor is dispositive, plaintiff has failed to demonstrate that Dr. Gray's methodology is reliable under *any* of the factors set forth by the Supreme Court." *Id.* at *23.

Frank v. New York 972 F. Supp. 130 (N.D. N.Y. 1997)

Factual Summary

Former state workers alleging multiple chemical sensitivity ("MCS") sued state and state agency employees for alleged violations of the Americans with Disabilities Act. Defendants moved to exclude proffered testimony of the plaintiffs' medical experts who were to testify that exposure to chemicals in the workplace created or aggravated

the plaintiffs' MCS condition. The court granted the motion, stating that, despite medical experts' opinions regarding the disorder, MCS was a speculative condition and not a generally accepted diagnosis in the medical community. Experts: Drs. Michael Lax, Eckardt Johanning, Carol Burgess, Mark Schimelman, Stuart Erner (medical doctors); and Drs. Charles Golden, Joan Gold, Maria Lifrak, Louis Calabro, and David Horenstein (psychologists), on diagnosis and causation.

Key Language

- "To the extent that the MCS theory has been tested, such tests have failed to provide objective support for the notion that the symptoms complained of by MCS sufferers are caused by environmental pollutants." Frank, 972 F. Supp. at 134.
- "[E]ven if the Court were to credit the authors' assertion that the study shows 'initial steps' in the direction of finding objective markers for MCS, we would be hesitant to conclude that such steps point to a definitive testing method sufficient to render an MCS diagnosis 'testable' within the meaning of *Daubert*." Id. at 135.

Third Circuit

Meadows v. Anchor Longwall & Rebuild, Inc. 306 F. App'x 781 (3d Cir. 2009)

Factual Summary

A mine worker who was injured by a malfunctioning shut-off valve fitting that had been replaced during a refurbishing project brought suit against the refurbishing company, who brought a third-party action against the manufacturer. To support their claims, the worker, along with his wife, who was also a plaintiff, offered the testimony of Mark A. Sokalski, P.E. on the issues of liability and causation. Sokalski opined that a defective valve exploded because of the refurbisher's failure to install a check valve that was part of the "longwall shield" placed in the mine to support the roof. To reach this conclusion, Sokalski examined, among other items, valves similar to the ones that had allegedly failed because of the lack of a check valve and applied "the principles of physics." The district court granted the refurbisher's motion in limine to exclude this testimony, concluding that it lacked an appropriate methodological foundation and was not sufficiently tied to the facts of the case. The Third Circuit affirmed, agreeing that Sokalski's methodology was unreliable.

Key Language

- "While a litigant must make more than a prima facie showing that his expert's methodology is reliable, we have cautioned that '[t]he evidentiary requirement of reliability is lower than the merits standard of correctness." *Meadows*, 306 F. App'x at 788 (quoting *Pineda v. Ford Motor Co.*, 520 F.3d 237, 248 (3d Cir. 2008)).
- "[I]n cases involving technical subjects like engineering, trial courts may consider relevant literature, evidence of industry practice, product design and accident history in evaluating reliability." *Id.*
- "[A]s the District Court points out, Sokalski's methodology was not reliable. Sokalski did not attempt to replicate the conditions in the longwall shield at the time of the accident... Sokalski did not examine the specific shield that Meadows was working on at the time of the accident... Further, there was no reference to material, publication or literature describing the failure scenario he presented, no evidence that his methodology was subjected to peer review or that it is generally accepted, no outside documentary evidence, aside from his own report, supporting his conclusions, no evidence concerning any known or potential error rates in his testing, and no control standards. Finally, Sokalski conceded that his pressure tests did not replicate the accident as he hypothesized that it had occurred... also his tests did not replicate the assembly of the hoses, connectors and Stecko block valve that existed in the mine because he did not use any hoses or connectors in his tests. Moreover, he did not research the maximum burst pressure of the hoses or connectors or otherwise test them with or without a check valve." Id. at 789.
- "[H]e speculated that had he used hoses and created a dynamic spike in pressure like the one he opines occurred in the accident the valve would have separated before the hoses would have blown. As the District Court noted, the expert's own testing did not support his hypothesis. Thus it was not the 'general physics principles' with which the District Court took issue, but rather the method by which Sokalski applied the principles to the facts of Meadows' accident.... Thus, the District Court properly excluded Sokalski's testimony...." *Id.* at 789–90

Pineda v. Ford Motor Co. 520 F.3d 237 (3d Cir. 2008)

Factual Summary

An automotive technician who was injured when the glass from the rear liftgate of a sport utility vehicle shattered brought a products liability action against

the manufacturer. To support his claim, the technician offered the testimony of Craig D. Clauser, P.E. Clauser opined that the glass shattered because of a defective design and that the manual and bulletins accompanying the vehicle lacked sufficient warnings and instructions. In reaching his warnings opinions, Clauser examined the service manual for the subject vehicle, concluding that it did not provide step-by-step instructions for replacing liftgate brackets and hinges and connecting them to the glass and did not warn that failing to follow the service manual was a safety issue. Clauser did not perform any objective testing. The manufacturer filed a motion to exclude Clauser's testimony, arguing, in part, that his methodology was unreliable. The district court granted this motion. Specifically, the district court concluded that his opinion was based solely on generalized experience, failed to offer alternative language for the warning, failed to test the effectiveness of an alternative warning, and failed to compare the language from the manual to that contained in the manuals for other manufacturers. The Third Circuit reversed, holding, inter alia, that the district court's "inquiry of the reliability of Clauser's methodology did not demonstrate the appropriate level of flexibility." Pineda, 520 F.3d at 248.

- "[A]n expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." *Pineda*, 520 F.3d at 247 (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994)).
- "While a litigant has to make more than a prima facie showing that his expert's methodology is reliable, we have cautioned that '[t]he evidentiary requirement of reliability is lower than the merits standard of correctness." *Id.* (quoting *In re Paoli*, 35 F.3d at 744) (alteration in original).
- "[T]he District Court focused too narrowly on Clauser's failure either to offer proposed alternative language for a warning or to test the effectiveness of alternative warnings. Pineda proffered Clauser as an engineering expert who understood the stresses and forces that might cause glass to fail. Clauser's specialized, rather than generalized, experience in this area allowed him to recognize that exerting a force on one area of the rear liftgate glass before exerting a force on another area of the glass could lead to its shattering. Clauser did not have to develop or test alternative warnings to render an opinion that the 2002 service manual did not provide adequate, step-by-step instructions to account for the differ-

- ent stresses that might be exerted when an automobile technician replaces the rear liftgate brackets and hinges, or that the lack of instructions was a safety issue for the technician." Id. at 248.
- The court also noted that "Clauser's opinion would probably be more reliable if he consulted the service manuals of other manufacturers and compared their language to Ford's 2002 service manual." Id. at 248 n.16.

Scrofani v. Stihl. Inc. 44 F. App'x 559 (3d Cir. 2002)

Factual Summary

A construction worker sustained burn injuries from an accident with a gasoline powered saw. In a products liability suit against the manufacturer, the district court rejected the opinion of the plaintiff's expert, Russell Fote, that the saw was defectively designed and contained inadequate warnings, concluding that the expert did not rely on a methodology in reaching conclusions, instead, he merely recited bald conclusions. The Third Circuit affirmed. Expert: Russell Fote (products liability).

Key Language

- Expert's "opinions were not based upon sufficient data, nor were they the product of reliable methods applied to the facts in a reliable manner; indeed, [the expert] 'employed absolutely no methodology at all,' merely setting forth 'a series of unsubstantiated opinions." Scrofani, 44 F. App'x at 562.
- "Even if the Court had concluded that [the expert] was a qualified expert, however, and it did not find that he was not, it would have been proper to exclude the evidence he proffered because, as noted above, he failed to base his conclusions on sufficient data and his methodologies were either nonexistent or wholly unreliable." Id.

Oddi v. Ford Motor Co.

234 F.3d 136 (3d Cir. 2000), cert. denied, 532 U.S. 921 (2001)

Factual Summary

The driver of a bread delivery truck brought a products liability action against the vehicle manufacturers. The plaintiff offered testimony from an engineer alleging that truck was not crashworthy and that the defendants negligently failed to test the truck. The district court excluded this testimony. The Third Circuit affirmed, holding that because the engineer conducted

no tests, cited no literature, and based conclusions on little more than personal intuitions, it was properly excluded. Experts: John N. Noettl (accident reconstruction/design engineer); Leon Kazarian (biomechanical engineering consultant).

Key Language

- "Although *Daubert* does not require a paradigm of scientific inquiry as a condition precedent to admitting expert testimony, it does require more than the haphazard, intuitive inquiry that Noettl engaged in. Given Noettl's responses, Oddi could not establish the existence of Noettl's methodology and research let alone the adequacy of it." *Oddi*, 234 F.3d at 156.
- "Methodology is defined as 'body of methods, rules, and postulates employed by a discipline: a particular procedure of set of procedures." Id. (quoting Webster's Ninth New Collegiate Dictionary 747 (1990)).
- "Since Noettl conducted no tests and failed to attempt to calculate any of the forces on Oddi or the truck during this accident, he used little, if any, methodology beyond his own intuition. There is nothing here to submit to peer review, and it is impossible to ascertain any rate of error for Noettl's assumptions about the forces that caused Oddi's horrific injuries." *Id.* at 158.

Elcock v. Kmart Corp. 233 F.3d 734 (3d Cir. 2000)

Factual Summary

A patron of a department store brought premises liability action to recover for injuries sustained when she slipped and fell in store. The district court held that proffered testimony from an economist regarding lost future earnings was admissible. The Third Circuit reversed on this decision, concluding that the testimony was based on assumptions wholly without foundation in the trial record, and thus was improperly admitted. Experts: Dr. Chester Copemann (vocational rehabilitation expert); Mr. Pettingill (economist expert).

Key Language

• The proposed expert's methodology was unreliable because such "testing did not generate consistent results" and was therefore, "subjective and unreproducible." Moreover, without an inkling as to the standards controlling the expert's method—*i.e.*, how he excludes for other variables, such as Elcock's preexisting injuries or job limitations—an expert trying to reproduce the methods used would be lost. Because "Elcock had neither the need nor the opportunity to test [the expert's] methods in this manner, on the present record we conclude that the first and fourth *Daubert* factors suggest that [the expert's] method was unreliable and therefore his opinion would not 'assist the trier of fact to understand the evidence or to determine a fact in issue...." *Elcock*, 233 F.3d at 747 (quoting Fed. R. Evid. 702).

In re TMI Litig. 193 F.3d 613 (3d Cir. 1999)

Factual Summary

Area residents who allegedly developed radiation-induced neoplasms as result of nuclear reactor accident at power plant brought personal injury actions against plant's owners and operators, companies that provided design, engineering, or maintenance services for plant, and vendors of equipment or systems installed in plant. After proceedings were consolidated, defendants moved for summary judgment. The district court granted the motion. The Third Circuit held that the proffered scientific testimony of various experts was properly excluded as unreliable or as unhelpful to finder of fact.

Key Language

- "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." *In re TMI Litig.*, 193 F.3d at 662.
- "Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertaining to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id.*
- "The test of admissibility is not whether a particular scientific opinion has the best foundation, or even whether the opinion is supported by the best methodology or unassailable research. Rather, the test is whether the 'particular opinion is based on valid reasoning and reliable methodology.' The admissibility inquiry thus focuses on principles and methodology, not on the conclusions generated by the principles and methodology." *Id.* at 655 (citing *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)).

Hoang v. Funai Corp., Inc. 652 F. Supp. 2d 564 (M.D. Pa. 2009)

Factual Summary

Homeowners filed products liability action against

manufacturer, alleging that they suffered personal injuries and property damage resulting from a fire caused by a purported defect in their combination television/ video cassette recorder. The plaintiffs offered the testimony of two experts, Bradley A. Schriver and Ronald J. Panunto, to support their claims. Both experts generally employed the methodology for fire cause and origin investigation outlined in National Fire Protection Association 921, Guide for Fire and Explosion Investigations ("NFPA 921"). The manufacturer filed a motion in limine to exclude both experts' testimony, arguing that the methodology they used was unreliable. Specifically, it argued that Schriver's methodology was aimed at corroborating the conclusions of prior investigators, did not appear in his report, relied on improper sources, and ignored physical evidence. As to Panunto, it argued that he "piggy-back[ed]" on Schriver's conclusions and was unreliable because he failed to visit the scene. The court concluded, in part, that NFPA 921 provided a reliable methodology, Schriver and Panunto properly applied it, and they relied on appropriate sources. Thus, the court denied the manufacturer's motion.

- "Several courts, including this one, have recognized that NFPA 921 offers a comprehensive and detailed treatment for fire investigation and have held its methodology is reliable for purposes of Rule 702." Hoang, 652 F. Supp. 2d at 567.
- "[T]here is no reference to the methodology guiding Schriver's fire investigation in his report. Despite this, Schriver testified that his investigation was guided by the NFPA 921 guidelines and the report makes clear that he is conducting an 'origin and cause' investigation. Based on the description of steps he took during his investigation, it appears that he was following the NFPA 921 standards. As noted above, the NFPA 921 methodology is widely considered to be reliable for purposes of Rule 702. Accordingly, the Court finds that Schriver employed a methodology that was subject to peer review, had a known or potential rate of error, could be measured against existing standards, and is generally accepted." *Id.* at 570 (internal citations to the record omitted).
- "[A] district court still must consider an expert's conclusions to assess whether they could reliably flow 'from the facts known to the expert and the methodology used." *Id.* at 571 (quoting *Oddi v. Ford Motor Co.*, 234 F.3d 136, 146 (3d Cir. 2000)).
- "[R]eliable sources of methodology on fire investigation appear to condone review of previously conducted investigations along with the interviewing of

- witnesses and other knowledgeable persons as a viable 'data collection method." Id.
- "It is clear that the NFPA 921 guideline, which has been determined to provide a reliable method for fire investigation, endorses the process of elimination in certain circumstances." Id. at 574.

David v. Black & Decker (US) Inc. 629 F. Supp. 2d 511 (W.D. Pa. 2009)

Factual Summary

A consumer and his wife filed a products liability action against a circular saw manufacturer after he injured his hand while operating the saw. The plaintiffs alleged that a defective design allowed the saw to accidentally energize. To support this allegation, the plaintiffs offered the testimony of Kai Baumann, a mechanical engineer, who listed several design features not present on the subject saw that, in his opinion, rendered it defective. The manufacturer countered with the testimony of Dr. Gary Deegear, a medical doctor with experience in biomechanics and power toolrelated injury causation. Both parties moved to exclude the other's proffered expert. The court denied both motions, concluding that each expert's methodology, although imperfect, was reliable enough to warrant admission pursuant to Rule 702 and Daubert.

Key Language

- "Although both experts could have done more and their opinions may be vulnerable on crossexamination, this does not render their methodology patently unreliable. As with the qualifications prong, 'the standard for determining reliability is not that high, even given the evidentiary gauntlet facing the proponent of expert testimony under Rule 702." David, 629 F. Supp. 2d at 516 (quoting In re TMI Litig., 193 F.3d 613, 665 (3d Cir. 1999)).
- The court noted that the fact that both experts' "methodology might not satisfy every *Daubert* factor does not render that testimony per se inadmissible." Id. at 516 n.3.

Burke v. TransAm Trucking, Inc. 617 F. Supp. 2d 327 (M.D. Pa. 2009)

Factual Summary

The driver of a pickup truck that was involved in a crash with a commercial tractor trailer filed suit against the truck driver and his employer for damages resulting from the crash. To determine if the forces exerted on the plaintiff during the crash could cause

injuries, the plaintiff retained Dr. Mariusz Ziejewski, biomechanical engineer. After analyzing case-specific documentation and conducting testing, Dr. Ziejewski concluded, in part, that the forces of the crash were sufficient to cause a brain injury. The defendants filed a motion to exclude Dr. Zijewski's testimony, arguing, inter alia, that his methodology lacked scientific reliability. After conducting a hearing, the court held that Dr. Ziejewski employed a reliable methodology that "consisted of [a] testable hypothesis, was subjected to peer review, had a known or potential rate of error, was generally accepted, and the techniques were sufficiently established to be reliable." Burke, 617 F. Supp. 2d at 335.

Key Language

- "The focus is not upon the expert's conclusions, but rather upon his methodology; the issue is whether the evidence should be excluded because the flaw is large enough that the expert lacks good grounds for his or her conclusion." Burke, 617 F. Supp. 2d at 331.
- "[M]any of Defendants' arguments and criticisms of [the expert's] methodology and inputs used went more to the weight of the evidence... Mere weakness in the factual basis of an opinion bears on the weight of the evidence, not its admissibility." Id. at 335.

Bauer v. Baver A.G. 564 F. Supp. 2d 365 (M.D. Pa. 2008)

Factual Summary

Thirteen beekeepers brought an action against an insecticide manufacturer, claiming that alleged exposure to the active ingredient in this insecticide, imidacloprid, through a liquid treatment to canola seeds prior to planting decimated their honeybee populations. The plaintiffs retained Dr. Daniel F. Mayer to investigate and opine as to the cause of the death of their bees. Dr. Mayer offered two opinions. First, he opined that imidacloprid from the manufacturer's pretreated seeds migrates into honeybee wax, which, over time, accumulates in hives and kills the bees. Second, he opined that the level of imidacloprid found in the hives of affected bees was sufficient to cause an adverse effect on them. In a motion to exclude Dr. Mayer's testimony, the manufacturer challenged the methodology underlying both of these opinions. With respect to his first opinion, the manufacturer argued that Dr. Mayer's methodology relied upon a critical assumption unsupported by either literature or testing. With respect to his second opinion, the manufacturer argued that Dr. Mayer's methodology did not account for other potential causes and failed to relate his opinions to research

data supporting a dose-response relationship. The court agreed on both counts and excluded Dr. Mayer's opinions in their entirety.

Key Language

- "[A]n expert opinion must be based on reliable methodology and must reliably flow from that methodology and the facts at issue—but it need not be so persuasive as to meet a party's burden of proof or even necessarily its burden of production." *Bauer*, 564 F. Supp. 2d at 375 (quoting *Heller v. Shaw Indus.*, *Inc.*, 167 F.3d 146, 152 (3d Cir. 1999)).
- "An expert's opinion must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation." *Id.* at 378.
- "Testing a theory, of course, is not always necessary to show that an expert employed a reliable methodology. But an expert must offer 'a good explanation as to why his or her conclusion remained reliable' notwithstanding the absence of testing." *Id.* at 379 (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 760 (3d Cir. 1994)) (internal citation omitted).
- "Where, as here, an expert's hypothesis is confirmed neither by scientific literature nor by proper testing, the expert's proffered testimony remains 'speculative and unreliable." *Id.* at 380 (quoting *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 322 (3d Cir. 2003)).
- "Another important factor in evaluating an expert's testimony is precision. 'Broad generalizations are far more difficult to corroborate than precise statements and have little explanatory power.... If severe and varied tests are the best indicator of validity, it follows that broad generalizations that can account for any possible state of affairs, and thus cannot be empirically tested, are not as good." *Id.* at 382 n.15 (quoting *In re TMI Litig. Consol. Proceedings*, No. Civ. 1-CV-88-1452, 1995 WL 848519 (M.D. Pa. Nov. 9, 1995)) (alterations in original).

Perry v. Novartis Pharms. Corp. 564 F. Supp. 2d 452 (E.D. Pa. 2008)

Factual Summary

The parents of a child diagnosed with lymphoblastic lymphoma brought a products liability action against the manufacturer of a drug the child was taking to treat eczema, alleging that this drug caused his lymphoma. Dr. Martyn T. Smith, a toxicologist, and Dr. E. Anders Kolb, a specialist in pediatric hematology and oncology, were two of the plaintiff's experts. Each provided opinions as to both general causation, that the drug at issue was capable of causing the type of harm

suffered by the child, and specific causation, that the child's use of the drug was a contributing factor to the development of his lymphoma. The manufacturer filed a motion to exclude their testimony on the grounds that the methodology by which they reached their opinions was unreliable. As to their general causation opinions, the court concluded that Dr. Smith's opinion, while ignoring key data, had a sufficiently reliable basis because it identified several applicable animal studies. The court stated that Dr. Kolb's general causation opinion, on the other hand, was based on "mere guesswork," rather than a scientifically valid methodology. Perry, 564 F. Supp. 2d at 469. As to their specific causation opinions, both experts used the same methodology-methodology that the court rejected as an improper and unreliable attempt at a differential diagnosis. Because, in addition to these methodological problems, both experts' opinions lacked "fit," the court granted the manufacturer's motion in its entirety and excluded the testimony of both Dr. Smith and Dr. Kolb.

- "The need for good grounds... 'means that *any* step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *Perry*, 564 F. Supp. 2d at 459 (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994)).
- "It is also true that the expert's journey from general causation to specific causation need not be just a two-step process. So long as, taken together, the experts are able to draw a chain of scientifically-reliable causal links that meets plaintiffs' requirements under the substantive tort law, the evidence is admissible and it will be left to the jury to establish the relative credibility of the parties' competing experts. Where, however, the expert reports leave wide, unexplained gaps in the causal chain, the evidence is not helpful to the trier of fact and must be excluded." *Id.* at 464.
- "Epidemiology is the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or a disease." Thus, while an expert's conclusions reached on the basis of other studies could be sufficiently reliable where no epidemiological studies have been conducted, no reliable scientific approach can simply ignore the epidemiology that exists." *Id.* at 465 (quoting *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 532 (W.D. Pa. 2003)).

- "It therefore appears that Dr. Smith's analysis of [a prior study] focused not on the findings that were most relevant to the hypothesis he sought to test but on the findings that were most helpful to his paying client. While this approach is, sadly, not uncommon, it is incompatible with the reliable application of the scientific method." Id. at 466.
- "[W]e must make clear that the non-existence of good data does not allow expert witnesses to speculate or base their conclusions on inadequate supporting science. In cases where no adequate study shows the link between a substance and a disease, expert testimony will generally be inadmissible, even if there are hints in the data that some link might exist. This may mean that early victims of toxic torts are left without redress because they are unable to prove their cases with the scientific data that exists. While this is a regrettable result in those individual cases, it is an unavoidable reality of the structure of our legal system and is necessary to protect the interests of defendants who might otherwise be subject to crippling verdicts on the basis of slender scientific evidence." Id. at 467-68.
- "While such speculation is appropriate in the laboratory where a hypothesis can be tested by experiment, it has no place in the courtroom where no such testing is possible." Id. at 469.

Floorgraphics v. News Am. Mktg. In-Store Serv. 546 F. Supp. 2d 155 (D. N.J. 2008)

Factual Summary

The plaintiff and defendants were competing companies in the in-store marketing industry. The companies entered contracts with retailers to install ads on the shelves and floor of their stores, as well as sold and placed ads for consumer packaged goods manufacturers in those stores. The plaintiff alleged that the defendants engaged in various practices to interfere with its contracts with retailers, including providing false and misleading information to its clients and hacking into its password-protected website. To support these claims, the plaintiff offered numerous experts, including John Wills, a purported damages expert who opined as to the lost profits attributable to the defendants' conduct, and Edward McLaughlin, a purported expert in industry standard operations and practices, who opined that the defendants' conduct substantially impaired the plaintiff's business. The defendants filed motions in limine seeking to exclude all of the plaintiff's experts, including Wills and McLaughlin, arguing, in part, that they used unreliable and flawed methodologies. The court

denied the motion directed at Wills, concluding that his "before and after" approach, although imperfect, could be adjusted to account for incorrect assumptions and therefore was a methodology that comported with both Rule 702 and Daubert. The court granted the motion directed at McLaughlin, holding that he "failed to use an acceptable methodology to establish causation." Floorgraphics, 546 F. Supp. 2d at 177. Specifically, he based his opinions on a survey of an insufficiently random indeed, a biased—population and did not observe a verbatim reporting protocol for the responses he received. Thus, the defendants' motions were granted-in-part and denied-in-part.

- "[I]t must be noted that the 'before and after' method is recognized by experts in the field as an acceptable method to calculate lost profits." Floorgraphics, 546 F. Supp. 2d at 172.
- "The [Reference Manual on Scientific Evidence], like Daubert, does not call for exclusion but rather an adjustment if there is reliance on a standard methodology that omits a relevant factor." Id.
- The court noted that when challenging an opposing party's proffered expert testimony, "a party must move beyond empty criticisms and demonstrate that a proposed alternative approach would yield different results." Id.
- · According to the court, "[t]here are well established principles to determine whether a survey is based on the 'methods and procedures of science." Id. at 179 (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (3d Cir. 1994)). Specifically, "[a] survey 'must be conducted with proper safeguards to insure accuracy and reliability.' These include the following: (1) a proper universe must be examined and a representative sample must be chosen; (2) the persons conducting the surveys must be experts; (3) the data must be properly gathered and accurately reported; (4) the sample design, the questionnaires, and the manner of interviewing must meet the standards of objective surveying and statistical techniques; (5) the survey must be conducted independently of the attorneys involves in the litigation; and (6) the interviewers ideally should be unaware of the purposes of the survey or litigation." Id. at 179 (quoting Pittsburgh Press Club v. United States, 579 F.2d 751, 755-59 (3d Cir. 1978)).
- "Although 'executive interviewing' may be an acceptable method of gathering information in the in-store marketing industry, it is not an acceptable methodology in a federal court of law, at least not as presented here." Id. at 180.

Fisher v. Clark Aiken Matik, Inc. 2006 WL 140424 (M.D. Pa. 2006)

Factual Summary

The executor of the plaintiff's estate brought suit against the manufacturer of an industrial paper "splicer/ sheeter" after the plaintiff was killed while trying to dislodge a broken potentiometer chain from the malfunctioning equipment. The plaintiffs claimed that the design of the equipment did not prevent, inhibit, or warn workers not to enter the area where the plaintiff was killed. The defendants filed a motion to exclude the testimony of the plaintiff's expert as the product of general knowledge, not the result of reliable principles and methods. The court ruled that Dr. Hutter's testimony was admissible, except for any testimony regarding the alleged premature failure of the potentiometer chain and associated product design issues. Expert: Gary M. Hutter, P.E., Ph.D., C.S.P. (mechanical engineering).

Key Language

- "Marquip contends that the other opinions expressed by Dr. Hutter are not premised upon reliable methodology. Recognizing that the *Daubert* factors are generally not applicable in technical fields such as engineering, the Hon. Joseph Irenas has identified helpful indicia of reliability that are helpful in the setting presented here. They include: (1) federal design and performance standards; (2) standards established by independent standards organizations; (3) relevant literature; (4) evidence of industry practice; (5) product design and accident history; (6) illustrative charts and diagrams; (7) data from scientific testing; (8) the feasibility of suggested modification; and (9) the risk/ utility of suggested modification." *Fisher*, 2006 WL 140424, at *5.
- "Assessment of Dr. Hutter's opinions in the context of these indicia of reliability compels a determination that his opinions are admissible. His opinions are linked to OSHA, ANSI, and NSC standards. He also references industry practice. His opinions are supported by computer generated animations and diagrams." *Id.*

Winnicki v. Bennigan's 2006 WL 319298 (D. N.J. 2006)

Factual Summary

The plaintiffs claimed that a salad their daughter ate at Bennigan's caused food poisoning, dehydration and, ultimately, her death due to kidney failure. The plaintiffs sought to introduce the testimony of Dr. Constantinescu to support their claim that the food poisoning and their daughter's renal failure were linked. The court concluded that Dr. Constantinescu's differential diagnosis was reliable. Expert: Dr. Alexandru Constantinescu (pediatric nephrology), Dr. Trachtman (pediatric nephrology), Dr. Dupont (infectious disease).

Key Language

- "Plaintiffs assert that neither of Defendant's experts challenge Dr. Constantinescu's methodology, and in fact, Dr. Trachtman agrees with Dr. Constantinescu's differential diagnosis. Plaintiffs further assert that despite Defendant's issues with Dr. Constantinescu's conclusions, Defendant has failed to propose, (through its experts), any alternate causes of Tara's Illness." Winnicki, 2006 WL 319298, at *12.
- The defendants fail to offer any alternative causes for the plaintiff's illness. "Only 'where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause' is that doctor's methodology considered unreliable. Therefore, in conducting a reliable differential diagnosis, Dr. Constantinescu was not required to rule out all alternative possible causes of Tara's illness." *Id.* at *13 (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999)).

Willis v. Besam Automated Entrance Sys., Inc. 2005 WL 2902494 (E.D. Pa. 2005)

Factual Summary

The plaintiff contended that she was injured when one of the panels of a revolving door at a hotel struck her and caused her to fall. The plaintiff also asserted that after she fell, the door continued to rotate and pushed her for several feet along the floor. To support these allegations, the plaintiff sought to introduce expert testimony that the hotel intentionally disabled the door's safety devices, that the door was defectively designed because it did not have a handicap speed actuation device, and that the "Automatic Door—Caution" signs provided inadequate warning of the door's potential hazards. The court excluded all of the plaintiff's expert testimony, ruling that it was not based on sufficiently reliable research methods and would not assist the jury. Expert: Ronald Panunto, P.E., C.F.E., I. (engineering).

Key Language

• "In this particular case, forming an expert opinion by mere reliance on the discovery materials does not constitute a sound methodology... instead of con-

- ducting his own independent investigation, Panunto merely relies on documents provided to him by Plaintiff's counsel." Willis, 2005 WL 2902494, at *5.
- "In this case, Panunto does not support his conclusions through any generally accepted methodology. Panunto conducted no tests, did not examine the subject door, never examined any similar door, and had no experience with the safety devices on the subject door. He used little, if any, methodology beyond his own intuition." Id. at *6.

Wicker v. Consol. Rail Corp. 371 F. Supp. 2d 702 (W.D. Pa. 2005)

Factual Summary

Railroad workers sued a railroad under the Federal Employer's Liability Act (FELA) seeking compensation for injuries sustained after exposure to toxic chemicals including asbestos, TCA, TCE, and benzene. The defendants submitted a motion to exclude the testimony of the plaintiffs' experts, arguing that their opinions were based on an unreliable methodology. The court granted-in-part and denied-in-part this motion. Experts: Michael J. Ellenbecker, Sc.D. (withdrawn by plaintiffs); George M Perovich, Ed.D. (withdrawn by plaintiffs); David O. Wilson, M.D. (occupational disease); Lisa Morrow, Ph.D. (psychology); and Michael LeWitt, M.D. (occupational medicine); John J. Shane, M.D. (pathologic anatomy & chemical pathology); and Allene J. Scott, M.D. (occupational medicine).

Key Language

- "Applying the eight factors listed earlier in this opinion, the Court makes the following conclusions regarding Dr. Kopstein's method: the diffusion method employed here has been tested, peer reviewed and used consistently in the field of chemistry so as to be reliable, and is not in error. This Model is recognized as generally accepted in the chemical engineering community for determining the rate of diffusivity.... Although not necessarily a technique, but more of a standard proven formula that is clearly reliable, the Model is used by chemists outside of litigation in the field of chemistry and by qualified chemical engineers such as Dr. Kopstein." Wicker, 371 F. Supp. 2d at 717.
- "The Reference Manual on Scientific Evidence (2d ed. 2000) recognizes three means of measuring exposure of chemicals to human beings: Evidence of exposure is essential in determining the effects of harmful substances. Basically, potential human exposure is measured in one of three ways. First, when

direct measurements cannot be made, exposure can be measured by mathematical modeling, in which one uses a variety of physical factors to estimate the transport of the pollutant from the source to the receptor. For example, mathematical models take into account such factors as wind variations to allow calculation of the transport of radioactive iodine from a federal atomic research facility to nearby residential areas. Second, exposure can be directly measured in the medium in question—air, water, food, or soil. When the medium of exposure is water, soil, or air, hydrologists or meteorologists may be called upon to contribute their expertise to measuring exposure. The third approach directly measures human receptors through some form of biological monitoring, such as blood tests to determine blood lead levels or urinalyses to check for a urinary metabolite, which shows pollutant exposure. Ideally, both environmental testing and biological monitoring are performed; however, this is not always possible, particularly in instances of past exposure." Id. at 719.

Ortiz v. Yale Materials Handling Corp. 2005 WL 2044923 (D. N.J. Aug. 24, 2005)

Factual Summary

The plaintiff was injured while using an open back, rear entry, stand-up forklift truck to place a couch on a rack while working at IKEA. The forklift's overhead guard pinned the plaintiff's foot after the forklift tipped over. The plaintiff brought a design defect and product liability claim against the manufacturer and distributor of the forklift. The defendant moved to exclude the testimony of the plaintiff's expert as unreliable and that the limited testing done by the expert did not fit with the facts of the case. The court granted this motion. Expert: John B. Sevart (mechanical engineering).

- "Sevart's simple review of the numbers in the chart, which does not incorporate any kind of statistical or mathematical analysis, offers no substantial support for his opinion that operators are safer staying inside a forklift rather than jumping out during a lateral tip-over, and that a stand-up forklift should come equipped with a rear door and a warning." Ortiz, 2005 WL 2044923, at *7.
- "The court finds incredulous Sevart's position that there is no way to test and obtain reliable answers in the area of forklift safety and lateral tip-overs without using human subjects... such computer-generated evidence has long been accepted as an appropriate

means to communicate complex issues to a lay audience, so long as the expert's testimony indicates that the processes and calculations underlying the reconstruction or simulation are reliable." *Id.* at *9.

Westley v. Ecolab, Inc. 2004 WL 1068805 (E.D. Pa. 2004)

Factual Summary

The plaintiff claimed that a cleaning solution manufactured by the defendants caused second and third degree burns to his feet and ankles when it spilled on his pants and shoes as he was preparing to mop his employer's kitchen floor. The plaintiff sought to introduce expert testimony to prove that the cleaning solution caused his injuries and that the defendant breached its duty to instruct foreseeable users on the safe use of its product and failed to warn foreseeable users of the dangers associated with its product. The defendant moved to exclude the testimony of both experts on the grounds that their opinions were not supported by any generally-accepted methodologies, testing, or literature and the experts could not rule out other causes. The court held that the testimony of both experts was admissible, as their opinions were based on general experience, scientific knowledge, and medical and scientific reports. Experts: Dr. Michael J. Coyer (toxicology), Dr. Burton Z. Davidson (chemical engineering, chemical kinetics, safety engineering).

Key Language

• "Defendant contends that the standards espoused under the theory of product stewardship do not apply because Ecolab is an inherently different chemical manufacturer than Dow Chemical, the company that developed the stewardship theory... Since the concept of 'product stewardship' appears to be an accepted industry standard in the area of chemical safety, Dr. Davidson's testimony with regard to this standard is not inappropriate." Westley, 2004 WL 1068805 at *11.

Soldo v. Sandoz Pharms. Corp. 244 F. Supp. 2d 434 (W.D. Pa. 2003)

Factual Summary

A manufacturer in a drug product liability case moved for summary judgment on issues of medical causation. The district court granted the motion. Experts: Drs. Buchholz, Savitz, Petro, Flockhart, Kulig, Powers.

Key Language

• "Plaintiffs' experts have not demonstrated that the

- methodology utilized in making these 'causality assessments' is scientifically reliable or that they even know what the methodology is." *Soldo*, 244 F. Supp. 2d at 513.
- "This Court concludes that plaintiffs' experts' reliance on anecdotal case reports to support their causation opinions is contrary to both good scientific practice and the *Daubert* case law. Such testimony is not 'scientific knowledge' and will not assist a trier of fact, and the data are not of a type reasonably relied upon by experts in the field...." *Id.* at 543.

Magistrini v. One Hour Martinizing Dry Cleaning 180 F. Supp. 2d 584 (D. N.J. 2002)

Factual Summary

A former employee brought a products liability action against her employer, as well as the manufacturer of dry cleaning fluid, for injuries she sustained while employed at a dry cleaner. The parties cross-moved to exclude expert testimony. The district court held that the plaintiff's physician's application of weight-of-the-evidence methodology was flawed, did not use a reliable scientific methodology in determining that perchloroethylene (PCE) was more likely than cigarette smoke to have caused leukemia, and that the reasoning and methodology of the defendant's physician were reliable. As a result, the motions were granted in part and denied in part. Experts: Michael D. Green (epidemiology); Dr. David Ozonoff (oncology, hematology, pharmacology, toxicology, epidemiology).

- "Daubert explains that the language of Rule 702 requiring the expert to testify to scientific knowledge means that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." Magistrini, 180 F. Supp. 2d at 594 (citing Daubert, 509 U.S. at 590).
- "This Court draws on the Third Circuit's discussion of the reliability of the differential diagnosis methodology in *Paoli* as instructive in this context. Importantly, because the weight-of-the-evidence methodology involves substantial judgment on the part of the expert, it is crucial that the expert supply his method for weighting the studies he has chosen to include in order to prevent a mere listing of studies and jumping to a conclusion. How else can one expert's choice of 'weight' be helpful to a jury which may be called on to assess a 'battle of weighers'? The partic-

ular combination of evidence considered and weighed here has not been subjected to peer review. However, the weight-of-the-evidence methodology has been used, in a non-judicial context, to assess the potentially carcinogenic risk of agents for regulatory purposes. The existence and maintenance of standards controlling the technique's operation when used for regulatory purposes is informative here." Id. at 602.

"While flexible application of the *Daubert* factors permits this Court to find that, properly applied, the weight-of-the-evidence methodology is not an unreliable methodology...." Id.

Pappas v. Sony Elecs., Inc. 136 F. Supp. 2d 413 (W.D. Pa. 2000)

Factual Summary

Owners of a television set brought a products liability action against the set's manufacturer, alleging that set caused a house fire. The manufacturer moved for summary judgment, asserting that the plaintiff's proposed expert's opinion was unreliable. The district court held that the engineer's testimony did not meet Daubert reliability requirement due to lack of evidence offered to support the engineer's methodology. Accordingly, it granted the motion. Expert: Richard Brugger (electrical engineer expert).

Key Language

- "It is not surprising that plaintiffs did not introduce evidence of a reliable methodology because Brugger himself stated that he was not required to follow any particular guidelines. For example, Brugger acknowledged that NFPA 921 is meant as a guide for fire investigators, yet he stated that '[i]t is not a rule. It is not a step by step procedure that each investigation must follow.' Additionally, he admitted that Kirk's Fire Investigation sets forth an established method for fire investigation, but felt that he was not 'obliged' to follow it." Pappas, 136 F. Supp. 2d at 424 (internal citation omitted).
- "For an expert's testimony to be admissible under Daubert, he must offer more than just his belief that every investigation is different. He must demonstrate that he employs a reliable methodology to each of these different investigations. In the present case, Brugger has simply not met this burden." Id.

Hamilton v. Emerson Elec. Co. 133 F. Supp. 2d 360 (M.D. Pa. 2001)

Factual Summary

A consumer brought a product liability action against a

saw manufacturer after part of his finger was severed. The manufacturer moved to exclude testimony of the consumer's expert witness. The district court held that the expert's testimony that the saw's brake did not work at time of accident and that therefore, brake was defective was not reliable as required by Daubert. As a result, it granted the motion to exclude. Expert: Stephen A. Wilcox, Ph.D. (products liability).

Key Language

• With regards to the expert's methodology, the court found that Dr. Wilcox "assumes that because the (saw's) brake did not work at the time of the accident. it was defective. Dr. Wilcox does not offer any discernible methodology that might have led to his conclusion that the brake did not work at the time of the accident. His 'method' consists only of the assumption that because the brake failed subsequent to the accident, it must have failed at the time of the accident. Therefore, he has not shown that his hypothesis concerning the brake's malfunction could be tested." Hamilton, 133 F. Supp. 2d at 371-72.

Dombrowski v. Gould Elecs., Inc. 31 F. Supp. 2d 436 (M.D. Pa. 1998)

Factual Summary

Residents of a borough located near battery crushing and lead processing plant sued plant owner, alleging strict liability and medical monitoring claims. The defendant moved to preclude expert testimony regarding bone lead testing technology as related to residents' proposed medical monitoring program. The district court held that expert testimony regarding bone lead testing technology in connection with proposed medical monitoring program was not admissible under Daubert. Experts: John F. Rosen, M.D. and Paul Mushak, Ph.D. (for the plaintiffs); Charles E. Becker, M.D., Raymond D. Harbison, Ph.D., and Ivor L. Preiss, Ph.D. (for the defendant).

- With regards to expert's testimony, the court stated that the "lack of proof and reliability was demonstrated by the fact that no one testified in this case who corroborated plaintiffs' expert witness' proposed use of KXRF methodology as a viable clinical tool, that is, in treating people or discovering disease." Dombrowski, 31 F. Supp. 2d at 443.
- "At best, the testimony and evidence could lead one to conclude that it is a valuable experimental tool and can be valuably used in research. In addi-

tion, we note, again, concerning the reliability of the instrument and methodology that there are significant problems with potential errors in the use of this methodology that could mislead or misinform patients and the community about levels of bone lead that might lead to other medical problems. " *Id.*

Belofsky v. General Elec. Co. 1 F. Supp. 2d 504 (D. V.I. 1998)

Factual Summary

The plaintiff brought a products liability action against refrigerator manufacturer under design defect and failure to warn theories for injuries she allegedly sustained when one of refrigerator's doors closed by itself with enough force to crush the plaintiff's thumb. The plaintiff moved for reconsideration after an order was issued granting manufacturer's motion to exclude testimony of plaintiff's expert. The district court held that the expert's proposed testimony that the door closed by itself, and that design of refrigerator created dangerous "pinch point," was inadmissible. Expert: Erwin Leshner (engineer expert).

Key Language

• In "this case, the analytical gap amounts to an 'analytical chasm' between the data that a heavily loaded refrigerator door when forcibly closed could crush a carrot and Leshner's opinion that the refrigerator was defectively designed and that the defect could have caused Belofsky to crush her thumb in the door." *Belofsky*, 1 F. Supp. 2d at 507.

Reiff v. Convergent Techs. 957 F. Supp. 573 (D. N.J. 1997)

Factual Summary

A secretary brought a products liability action against a computer keyboard manufacturer, claiming that defects in keyboard caused the secretary's carpal tunnel syndrome. The defendant moved to preclude the plaintiff's expert testimony. The district court granted the motion. Experts: Alan Hedge, Ph.D. (engineer and ergonomist); Karl H.E. Kroemer, Ph.D. (engineer and ergonomist); Robert J. Cunitz, Ph.D. (human factors psychologist); Gary M. Goldstein, M.D. (physician).

Key Language

"Applying the *Daubert-Paoli* factors, Dr. Hedge's
methodology proves unreliable. Even if one assumes
that Dr. Hedge's hypothesis—that defendants' keyboard substantially caused Mrs. Reiff's injuries—is
testable through an ergonomic analysis of the vari-

ous factors affecting her typing activity, Dr. Hedge conducted no such analysis. He did not observe Mrs. Reiff's typing technique or posture, question her about her work habits, determine the configuration of her workstation, or evaluate the kind of material she typed at her computer keyboard." *Reiff*, 957 F. Supp. 582–83.

 "Indeed, without knowing how hard Mrs. Reiff types, Dr. Hedge could not accurately determine whether defendants' keyboard or Mrs. Reiff's own typing technique was more responsible for the keyforces she expended typing." *Id*.

Rutigliano v. Valley Bus. Forms 929 F. Supp. 779 (D. N.J. 1996)

Factual Summary

A former office worker brought a products liability action against the manufacturers of carbonless carbon paper. The plaintiff alleged that she had developed "formaldehyde sensitization" from exposure to formaldehyde contained in the paper. After settlement with several manufacturers, two remaining manufacturers moved to bar the testimony of an expert witness and for summary judgment. The district court held that the testimony of a physician that exposure to paper had caused worker's condition was not admissible under *Daubert* with respect to issues of either general or specific causation. *Motions granted*. Experts: Elaine B. Panitz, M.D. (offers testimony that use of CCP can cause formaldehyde sensitization); Thaddeus J. Godish, Ph.D.

Key Language

- Reliance upon medical literature for conclusions not drawn therein is not an accepted scientific methodology. Dr. Panitz's method is not generally accepted by the scientific community. *Rutigliano*, 929 F. Supp. at 784.
- In light of the copious peer-reviewed literature determining that CCP does not cause the injuries that
 Dr. Panitz wishes to testify that it has caused, Dr.
 Panitz's failure to seek or obtain peer review of her
 theory weighs heavily against the reliability of her
 methods. *Id.* at 785.

Diaz v. Johnson Matthey, Inc. 893 F. Supp. 358 (D. N.J. 1995)

Factual Summary

A former employee brought suit against his former employer and former employer's parent corpora-

tion seeking damages for ongoing lung problems from platinum allergy from on-the-job exposure to platinum salts. The district court dismissed claims against employer and conspiracy claim against parent corporation, but fraud and negligence claims survived summary judgment. The district court granted the defendants' motion to strike the plaintiff's expert testimony. Expert: Dr. Donald Auerbach (pulmonologist).

Key Language

- "A judge decides whether the experts are reliable; the jury decides whether the experts are correct." Diaz, 893 F. Supp. at 359.
- "An opinion as to the source of a patient's illness is unreliable if either the [doctor] engaged in very few standard diagnosis techniques by which doctors normally rule out alternative causes *and* the defendant pointed to some likely cause of the plaintiff's illness other than the defendant's actions and the doctor offered no reasonable explanation as to why he or she still believed that the defendant['s] actions were a substantial factor in bringing about that illness." *Id.* at 376.

Wade-Greaux v. Whitehall Labs. 874 F. Supp. 1441 (D. V.I. 1994)

Factual Summary

A mother brought a products liability action on behalf of her child, who was born with limb deformity, against the manufacturer of a nasal decongestant which mother had taken during pregnancy. The manufacturer moved for summary judgment, alleging that opinions of expert witnesses for mother and child were inadmissible or insufficient as matter of law on issue of causation. The district court held that the methodology used in studies relied on by witnesses was required to be compared to methodology relied on by experts in study of human birth defects. The court noted that each study had express limitations and cautions, and that the experts could not reliably utilize these articles to support their conclusions as to general causation. Experts: Enid F. Gilbert-Barness, M.D. (pediatric pathologist, developmental pathologist and genetic pathologist); Stuart A. Newman, Ph.D. (professor of cellular biology and anatomy); Alan K. Done, M.D. (pediatrician, pharmacologist and toxicologist); John A. Tilelli, M.D. (pediatric and intensive care physician).

Key Language

• "In evaluating the scientific validity or reliability of a particular methodology, it is also appropriate for a trial court to consider whether the methodology

- is used in a non-judicial setting. If a methodology has not been put to any non-judicial use, that weighs against admissibility." Wade-Greaux, 874 F. Supp. at
- "There is no evidence that any of the methodologies employed by plaintiff's expert witnesses has been put to any use outside of the courtroom. Dr. Gilbert, for example, employs the community-accepted criteria when addressing her scientific peers, but has a different methodology when testifying in this matter. Similarly, at such time that Dr. Done made presentations in the field of teratology, he followed the accepted methodology. Drs. Tilelli and Palmer, meanwhile, do not engage in any activities in the field of teratology. Thus, these witnesses do not employ any methodology outside of the courtroom or subject their conclusions to critical peer review." Id.
- "In vivo and in vitro animal test data are unreliable predictors of causation in humans.... In vivo animal studies are unreliable predictors of results in humans for several reasons, including the facts that (a) many test animals are bred to be sensitive to a particular type of response; (b) there are differences between the dosages given to experimental animals and those taken by humans for therapeutic purposes and (c) animals have dramatically different physiology, biochemistry and metabolism pathways that break down the toxic chemicals so that, from species to species, there are differences in bioactivation and detoxification. In vitro test data is subject to the same deficiencies, but is even further removed from the human experience because the exposures do not replicate the human exposures." *Id.* at 1483–84.

Fourth Circuit

Pugh v. Louisville Ladder, Inc. 361 F. App'x 448 (4th Cir. 2010)

Factual Summary

A consumer brought a products liability action against a ladder manufacturer, claiming that he sustained injuries when the ladder failed, causing him to fall. The plaintiff's theory was that the ladder had a manufacturing defect, specifically, microscopic cracks at the rivets, that expanded over time until they eventually caused the buckling that caused the plaintiff to fall. In contrast, the manufacturer argued that the plaintiff tipped the ladder and that post-incident damage was caused by the plaintiff landing on top of the ladder. The plaintiff's experts concluded that the ladder had experienced a structural failure after conducting only

a visual inspection. After they reached this initial conclusion, they performed additional testing, including testing of the subject ladder, exemplar testing, and testing that purported to rebut the defense theory. They testified that this testing, combined with their experience, rendered their conclusions scientifically valid. The district court rejected the manufacturer's motion to exclude these experts and held that their testimony rested on a sufficient methodology that had been reliably applied. The Fourth Circuit affirmed.

Key Language

- "Although LL had referenced purported errors in Pugh's experts' methodology... LL's argument focused almost entirely on the contention that Pugh's experts' conclusions were readily falsifiable.... [T]he court was following this Court's instruction to focus on the experts' 'principles and methodology' and not on the conclusions reached." *Pugh*, 361 F. App'x at 453–54.
- "The Supreme Court has recognized that 'conclusions and methodology are not entirely distinct from one another' and that '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.' General Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). Such holding, however, does not shift the focus of the Daubert test to experts' conclusions, but merely clarifies that the district court's broad discretion includes the discretion to find that there is 'simply too great an analytical gap between the data and the opinion proffered.' Id. Our recent decision in Moreland, decided after Joiner and the 2000 amendments to Rule 702, reiterates the fact that the proper focus remains on the expert's 'principles and methodologies." Id. at 454 n.4 (quoting United States v. Moreland, 437 F.3d 424, 431 (4th Cir. 2006)).
- "In addition to testing and analysis supporting their crack propagation theory, Pugh's experts performed testing and analysis to disprove the opposing theory—impact damage. Based on their experience, Pugh's experts testified at the *Daubert* hearing that a blunt object, like a human's upper torso, falling onto an aluminum ladder could not create the buckling damage readily observable on the accident ladder. To prove such conclusion through testing, Pugh's experts conducted impact testing... Such impact testing, which was video-taped and thus subject to peer review, purportedly established that the damage apparent on the accident ladder could not have

- been caused by a person falling onto the ladder." *Id.* at 455–56 (internal citation omitted).
- "[I]n light of the testing that was performed to both support Pugh's hypothesis and discredit LL's hypothesis, and the lack of evidence suggesting that any of such testing was unreliable, the alleged failure of Pugh's experts to perform additional testing goes more to the weight of the expert testimony than to its *Daubert* admissibility." *Id.* at 456.

Simo v. Mitsubishi Motors N. Am., Inc. 245 F. App'x 295 (4th Cir. 2007)

Factual Summary

A passenger in a sport utility vehicle was injured when its driver over-corrected, it rolled over, then was subsequently struck by a tractor trailer. Prior to the crash, the passenger had been a highly-ranked freshman collegiate soccer player. The injuries he sustained in the crash prevented him from resuming his soccer career. The passenger brought a products liability action against the manufacturer, arguing that the vehicle was unreasonably dangerous because its center of gravity was too high. In addition to design experts, the plaintiff offered the testimony of two damages experts, who opined as to the plaintiff's lost future earnings. One of these purported experts, a soccer sports agent, opined that the plaintiff had a high-level skill set that made him highly desirable to professional teams. Based on the plaintiff's individual skill set and the agent's experience, he determined that the plaintiff likely would have earned \$3 to \$10 million during his soccer career. After a the jury returned a verdict in the plaintiff's favor, the manufacturer appealed, arguing, inter alia, that the district court improperly admitted testimony from the plaintiff's experts. The Fourth Circuit concluded that the testimony from the plaintiff's damages experts, even though it was based primarily on personal observations and experience, used a methodology that was sufficiently reliable to satisfy Rule 702 and Daubert. Accordingly, it affirmed.

- "[T]he inquiry into the reliability of an expert's methodology must be flexible and case-specific." *Simo*, 245 F. App'x at 301.
- "[T]he district court reasonably accepted that a soccer player's value can be reliably estimated by the personal observations and experience of a person whose job requires him to evaluate players' abilities and determine their value." *Id*.

Waytec Elecs. Corp. v. Rohm & Haas Elec. Materials 459 F. Supp. 2d 480 (W.D. Va. 2006), *aff'd*, 255 F. App'x 754 (4th Cir. 2007)

Factual Summary

A manufacturer of printed circuit boards sued the manufacturer and distributor of a chemical solution used for copper plating of printed circuit boards. After the solution was applied during the plaintiff's manufacturing process, the manufacturer experienced sporadic cracking in its circuit boards. As a result, the plaintiff brought fraud, breach of warranty, and other causes of action against the defendants. The plaintiff offered the testimony of several experts, including its process engineering manager Robert Welch, to support its argument that the chemical solution caused the cracking. This testimony was based almost exclusively on the fact that after the plaintiff switched to an alternative product, it did not have issues with circuit boards cracking. After the plaintiff presented its fraud case at trial, the court granted the defendants' motion for judgment as a matter of law, concluding that it had not presented any scientifically reliable evidence to support causation. Specifically, the court held that the methodology used by the plaintiff's experts was "based on correlation and guesswork," "utterly fail[ed] to consider or explain alternative causes," and suffered from similar deficiencies that rendered it unreliable. Waytec Elecs. Corp., 459 F. Supp. 2d at 488-89.

Key Language

• "Waytec argued that alternative causes suggested by a defendant normally affect the weight the jury should give the expert's opinion and not its admissibility. The court agrees; normally they do not. But as the Fourth Circuit noted in a case involving a medical diagnosis, an opinion 'that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.' See Westberry v. Gislaved, 178 F.3d 257, 265 (4th Cir. 1999). 'Thus, if an expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert's testimony.' Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 202 (4th Cir. 2001) (citing Westberry, 178 F.3d at 265-66). Essentially, that is the case here, as Waytec has offered no scientifically reliable evidence that proves that [the defendants' chemical solution], rather than a host of other possible causes, was the source of the cracking. Welch's belief utterly fails to consider or explain alternative

- causes. His belief is scientifically untestable." *Waytec Elecs. Corp.*, 459 F. Supp. 2d at 488–89.
- "It would confound logic and legitimate deductive reasoning to permit a jury to draw inferences concerning a technical subject matter that trained experts in the field cannot legitimately draw." *Id.* at 489.

United States v. Wilson 484 F.3d 267 (4th Cir. 2007)

Factual Summary

Three defendants were convicted of drug-related offenses. At trial, the government offered expert testimony from a detective as to the meaning of various drug code words. This detective's methodology for translating these terms was based on his experience and training, as well as his analysis of intercepted conversations to see if they contained words that appeared to have dual meanings. After the defendants were convicted, they appealed, arguing that the district court erred by admitting the detective's testimony because he did not adequately explain how his experience supported his methodology, which they argued was unreliable. Although it concluded that portions of this testimony was improper because it interpreted language that did not need interpretation, the Fourth Circuit held that the method employed by the detective, which focused on deciphering words based on their context, rather than seeking to give meaning to words under the assumption that they must be drug-related, was reliable and, given the detective's experience, had been reliably applied. Accordingly, it affirmed.

Key Language

- "A district court's reliability determination does not exist in a vacuum, as there exist meaningful differences in how reliability must be examined with respect to expert testimony that is primarily experiential in nature as opposed to scientific." *Wilson*, 484 F.3d at 274.
- "While a district court's task in examining the reliability of experiential expert testimony is therefore somewhat more opaque, the district court must nonetheless require an experiential witness to 'explain how [his] experience leads to the conclusion reached, why [his] experience is a sufficient basis for the opinion, and how [his] experience is reliably applied to the facts." *Id.* (quoting Fed. R. Evid. 702 advisory committee's note) (alterations in original).

Testerman v. Riddell, Inc. 161 F. App'x 286 (4th Cir. 2006)

Factual Summary

A college football player sued the defendant for allegedly fitting him with shoulder pads that were too small to protect him during a game. The plaintiff appealed the district court's exclusion of his expert witness and subsequent summary judgment, arguing that the trial court improperly focused on his expert's conclusions and that this expert's methodology was sound. The Fourth Circuit affirmed. Expert: Kent Falb (athletic trainer).

Key Language

- "The district court identified three key questions that Falb was unable to answer definitively: (1) which blow caused Testerman's injury; (2) whether the area of impact was covered by the shoulder pad; and (3) whether the injury would have occurred, or would have been substantially mitigated, had Testerman been wearing different pads. Testerman argues that the district court improperly concentrated on Falb's conclusions rather than on the reliability of the methods Falb used to reach those conclusions." *Testerman*, 161 F. App'x at 289.
- "It was appropriate for the district court to concentrate on this weakness in Falb's methods as well as on the other problems it enumerated when it held Falb's testimony to be inadmissible. Thus, the district court properly emphasized the unreliability of Falb's methods even though it looked to the conclusions those methods generated as evidence of unreliability." *Id.* at 289–90.

Stolting v. Jolly Roger Amusement Park, Inc. 37 F. App'x 80 (4th Cir. 2002)

Factual Summary

An amusement park patron fractured three vertebrae on water slide. In a suit against park, the plaintiff offered expert testimony from John H. Hanst, regarding the park's duty to warn and to instruct patrons on correct sliding position. The district court excluded this testimony, stating that the expert's investigations were cursory and he set forth no scientific principles on which his conclusions were based. The Fourth Circuit held that the expert's proposed testimony regarding amusement park's duty to warn patrons of specific dangerousness of water slide was not based on adequate technical, scientific investigation or analysis of accident. Accordingly, it affirmed. Expert: John H. Hanst (recreation maintenance supervisor).

Key Language

• "Hanst, however, did not set forth facts and scientific

principles or methods to support his conclusion that a specific warning was necessary or that the suggested body position was warranted. His testimony was nothing more than *ipse dixit*—bare conclusions without reliable support. Thus, the district court did not abuse its discretion in excluding Hanst's testimony as an expert." *Stolting*, 37 F. App'x at 83.

Phelan v. Synthes, Inc. 35 F. App'x 102 (4th Cir. 2002)

Factual Summary

A patient brought an action against a medical device manufacturer alleging breach of implied warranty of merchantability, strict liability, and negligence when an intramedullary nail was removed from the patient's leg after it fractured. In the plaintiff's suit against the manufacturer, the patient offered a biomechanical engineer's testimony that the nail was defective, unreasonably dangerous, and inadequately tested. The district court excluded this testimony. The Fourth Circuit affirmed, holding that the expert's testimony was too abstract and not sufficiently tied to facts of case. Expert: Dr. Joseph Dyro, Ph.D. in Biomedical Electronics Engineering from the University of Pennsylvania.

- "The district court excluded Dr. Dyro's testimony despite finding that he was 'a very accomplished man and... qualified to render expert opinions in a good many areas...' because he had not brought his expertise to bear on the issues in this case except in a very general way. In other words, the district court found that the reasoning or methodology underlying Dr. Dyro's opinions was not sufficiently specific to the issues at hand to render those opinions admissible." *Phelan*, 35 F. App'x at 107.
- "The trial court did not abuse its discretion in determining that this opinion was not supported by reliable methodology where Dr. Dyro's opinion was based largely on extrapolation from a simple principle of engineering without quantitative or otherwise specific examination of the properties of the Synthes nail itself." *Id.*
- "Because Dr. Dyro had no reliable basis on which to assert that the nail was defective and unreasonably dangerous, these opinions were likewise not sufficiently supported by reliable methodology. In sum, then, the district court did not abuse its discretion in excluding Dr. Dyro's proffered expert testimony." *Id.* at 108.

United States v. Rogers 26 F. App'x 171 (4th Cir. 2001)

Factual Summary

A criminal defendant objected to testimony from two Secret Service agents that latent print matched exemplar supplied by defendant, contending that no uniform standards governed fingerprint matching, but in fact such standards are supplied by training, peer review, and double checking. The district court admitted the testimony. The Fourth Circuit affirmed.

Key Language

• "To the extent that fingerprint analysis involves some measure of subjective interpretation by the examiner, the possibility of error was mitigated in this case by having two experts independently review the evidence. And although Rogers also claims no uniform standards exist to pinpoint exactly when a fingerprint match can be declared, such standards do exist through professional training, peer review, presentation of conflicting evidence and double checking, which is standard operating procedure with latent print examiners." *Rogers*, 26 F. App'x at 173.

Cooper v. Smith & Nephew, Inc. 259 F.3d 194 (4th Cir. 2001)

Factual Summary

The plaintiff filed suit against Smith & Nephew, Inc., claiming that its defective device was responsible for his failed back surgeries and the accompanying deleterious side effects. The plaintiff offered causation testimony from a physician expert who performed a differential diagnosis. The district court dismissed Cooper's claims after determining that Cooper had no admissible medical evidence indicating that Smith & Nephew's device was the proximate cause of his injuries. The Fourth Circuit affirmed this exclusion, holding that the expert's opinion was conclusory and not supported by any scientific method. As a result, the Fourth Circuit held that the district court did not abuse its discretion in excluding this testimony. Experts: Dr. Harold Alexander (biomedical engineering); William Mitchell, M.D. (orthopedic surgeon).

Key Language

• In this case, "Dr. Mitchell asserted what amounted to a wholly conclusory finding based upon his subjective beliefs rather than any valid scientific method. Dr. Mitchell has never implanted a pedicle screw device in his patients' spines because he believes them to be inherently dangerous. His position conflicts with that of the FDA and the majority of his colleagues in the American Academy of Orthopedic Surgeons who believe that the use of spinal instrumentation, including the use of pedicle screws, is the standard of care in the profession." *Cooper*, 259 F.3d at 200.

Talkington v. Atria Reclamelucifers Fabrieken BV 152 F.3d 254 (4th Cir. 1998)

Factual Summary

The plaintiffs sued the manufacturer of disposable butane cigarette lighters on theories of strict liability and negligence. The district court entered judgment against the manufacturer on the negligence theory. The manufacturer appealed and one of the plaintiffs crossed appealed. The Fourth Circuit upheld many of the district court's orders, including the admissibility of the plaintiffs' expert testimony. Experts: Arthur Sullivan and Ted Kaplon (fire cause and origin).

Key Language

- Sullivan's reasoning and methodology was valid because he "had considered the alternative scenarios for the fire's origin proposed by defendant, but that he ruled out gas, kerosene heaters, a smoldering cigarette, and arson as likely causes of the fire." *Talkington*, 152 F.3d at 264.
- "Kaplon defended his position and gave well-reasoned responses for rejecting defendant's alternative scenarios, including arson, a malfunctioning kerosene heater, and a dropped smoldering cigarette." *Id.*

Benedi v. McNeil-P.P.C., Inc. 66 F.3d 1378 (4th Cir. 1995)

Factual Summary

The consumer of a painkiller brought suit for negligent failure to warn and breach of warranty against the manufacturer of the painkiller. The plaintiff, who suffered severe liver damage, alleged that his ailment resulted from a combination of alcohol and acetaminophen (the substance the painkiller contained). The jury returned a verdict in favor of the plaintiff and awarded punitive damages. The district court denied manufacturer's motions for judgment as matter of law and for new trial and entered on the jury verdict. The manufacturer appealed. The Fourth Circuit affirmed.

Key Language

• "The testimony of the experts who concluded that consumer's liver failure was caused by a combina-

- tion of alcohol and acetaminophen based on the same methodologies used daily in treating patients was properly admitted under *Daubert* and supported finding of causation." *Benedi*, 66 F.3d at 1384.
- "The court would not declare methodologies invalid in light of medical community's daily use of the same methodologies." *Id*.
- The plaintiff's treating physicians based their conclusions on the following methodology: "microscopic appearance of his liver, the Tylenol found in his blood upon his admission to the hospital, the history of several days of Tylenol use after regular alcohol consumption, and the lack of evidence of a viral or any other cause of the liver failure." *Id*.
- "The plaintiff's other experts relied upon a similar methodology: history, examination, lab and pathology data, and study of the peer-reviewed literature." *Id*.

Perkins v. United States 626 F. Supp. 2d 587 (E.D. Va. 2009)

Factual Summary

The driver of an automobile that crashed into a vehicle driven by a Federal Bureau of Investigation employee filed suit against the United States, claiming that the FBI employee negligently changed lanes on the highway. The plaintiff offered the testimony of Dr. Arthur Wardell, an orthopedic surgeon, who opined as to the causation of the plaintiff's injuries and the future costs associated with those injuries. To reach his causation opinion, Dr. Wardell relied entirely on the plaintiff's self-report that her injuries were caused by the crash. He did not investigate her prior medical history, which would have revealed numerous prior trauma and injuries, as well as pre-existing medical conditions that could have affected the plaintiff. With respect to Dr. Wardell's opinion as to future costs, he could not provide any methodological basis. The court granted the government's motion in limine to exclude Dr. Wardell's testimony, holding that it rested of substantially flawed, or non-existent, methodology.

Key Language

- "Dr. Wardell's exclusive reliance on a patient's self-report fails to employ 'the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Perkins*, 626 F. Supp. 2d at 593 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).
- "Even if the medical profession does not fault Dr.
 Wardell for his reliance on Perkins' self-report, and
 in turn, his ignorance of Perkins'[] prior trauma and

- treatment, the law still demands that his expert testimony be reliable." *Id*.
- "Dr. Wardell's diagnosis of Perkins is driven by willful blindness to plausible, perhaps even probable, alternative explanations for his patient's symptoms and injuries. By selectively ignoring the facts that would hinder the patient's status as a litigant, Dr. Wardell reveals himself as the infamous 'hired gun' expert." *Id.* at 595.
- "[T]he Court also excludes Dr. Wardell's prognosis of future medical costs for Perkins. According to the evidence before the Court, the prognosis is nothing beyond a guess. Dr. Wardell does not provide any methodological basis for the prognosis." *Id*.

Gallagher v. S. Source Packaging, L.L.C. 568 F. Supp. 2d 624 (E.D. N.C. 2008)

Factual Summary

The plaintiffs, a trustee of a liquidation trust for a defunct packaging company and the packaging company, brought an action against the putative buyer for breach of an asset purchase agreement. The defendant purchased the company's assets out of foreclosure, and the purchase agreement contained a deferred payment clause. Citing alleged misrepresentations as to the financial condition of the company, the defendant did not make the deferred payment and argued that it could deduct any business losses from the deferred payment pursuant to a provision in the sales agreement. The defendant offered the testimony of Chuck Mueller, a software consultant, who opined that the plaintiffs' failure to obtain price increases from its customers resulted in lost revenue for the company. To calculate these losses, Mueller pulled old sales data from a company database using various parameters, reaching a figure that he opined represented the lost revenue caused by the plaintiffs' misrepresentations. Mueller recalculated this figure based on new parameters provided by the defendant. In the end, Mueller produced twelve different sets of results. Because of this flawed methodology, as well as unwarranted assumptions, the court granted the plaintiffs' motion to exclude Mueller's testimony.

Key Language

• "[T]here is no evidence that Mueller's method for determining losses is generally accepted by accountants or economists. There is no evidence of a known error rate for the methodology. There is no evidence that the methodology is subject to peer review. In fact, the only review that Mueller's methodology has been subject to is from Southern Source. Muel-

ler's deposition testimony reflects Southern Source's complete control over Mueller's methods and results. Southern Source simply gave Mueller some parameters, reviewed the results that these parameters generated, and then changed the parameters until Southern Source reached the desired results. Tellingly, Mueller has produced twelve different sets of results, ranging from approximately \$177,000 up to \$1.7 million in 'lost revenue.' Mueller's testimony changes to reflect whatever position Southern Source is currently taking as to lost revenue, and is patently unreliable." Gallagher, 568 F. Supp. 2d at 634–35 (internal citations omitted).

"Further, Mueller's original expert report and testimony are a cornucopia of flawed assumptions. For example, Mueller indiscriminately assumes that every failure to meet Southern Source's dictated price increase goal is [the plaintiff's] fault. Further, Mueller makes unsupported leaps of logic. For example, Mueller's methodology cannot detect any change in price that occurred between the first and last sales within the time frame that Southern Source dictated." Id. at 635 (internal citations omitted).

Doe v. Ortho-Clinical Diagnostics, Inc. 440 F. Supp. 2d 465 (M.D. N.C. 2006)

Factual Summary

The parents of a child brought suit against a drug manufacturer, alleging that a compound contained in a treatment the mother received while pregnant and immediately after giving birth caused the child to develop autism. To prove causation, the plaintiffs offered the testimony of Dr. Mark Geier, a specialist in obstetrical genetics, who provided both general and specific causation opinions. To reach his general causation opinion, Dr. Geier's methodology consisted of reviewing relevant literature and his own studies pertaining to the general incidence of autism. For his specific causation opinion, Dr. Geier used a differential diagnosis. The manufacturer filed a motion to exclude, arguing that this methodology did not satisfy Rule 702 or Daubert. The court agreed.

Key Language

• "Where proffered expert testimony is not based on independent research, but instead on such a literature review, the party proffering such testimony must 'come forward with other objective, verifiable evidence that the testimony is based on scientifically valid principles. One means of showing this is by proof that the research and analysis supporting the

proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication.' Thus, the research Dr. Geier relied upon must itself be able to meet the *Daubert* test. The fact that a journal is peer-reviewed is a significant consideration." Doe, 440 F. Supp. 2d at 470 (quoting Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1318 (9th Cir. 1995)).

- "[T]he Court notes that, in fact, a literature review can be an appropriate part of a method of determining general causation. However, a literature review must still be performed appropriately. As revealed by his testimony at the *Daubert* hearing, Dr. Geier, however, relied upon a number of disparate and unconnected studies... to reach a piecemeal conclusion with respect to general causation.... Dr. Geier's methodology consisted of attempting to connect various individual studies that had developed the existence of certain findings.... Thus, on its face, all these study results, when pieced together, would seem to support Plaintiffs' general causation theory, as offered by Dr. Geier... However, upon being subjected to extensive cross examination, much of Dr. Geier's analysis, based upon his collective review of a motley assortment of diverse literature, proved, in the Court's view, to be overstated." Id. at 473-74 (internal citations and footnotes omitted).
- "[W]hile Dr. Geier's presentation of the literature as part of his methodology might at first glance appear convincing, the disconnected literature he presents does not add up to the opinion and conclusion that Dr. Geier is offering. Accordingly, the Court finds that Dr. Geier's literature review, in this instance, does not meet the Daubert standard of being both derived by the scientific method and relevant to the 'task at hand." *Id.* at 475 (internal citations omitted).
- "Generally, it is not appropriate to rely on a differential diagnosis to prove general causation." *Id.* at 477.

Tunnell v. Ford Motor Co. 330 F. Supp. 2d 731 (W.D. Va. 2004)

Factual Summary

The plaintiff suffered serious injuries after the vehicle, in which he was a passenger, hit a utility pole. His leg broken and pinned by the wreckage, the plaintiff could not get out of the vehicle before the passenger compartment caught fire, burning him severely. The defendants sought to introduce expert testimony to support the assertion that source of the fire was not electrical, that the plaintiff was intoxicated at the time of the accident, and that the plaintiff's expectations of a batterydisconnect device were not consistent with consumer safety expectations. The court admitted the fire cause and origin opinions of Andrew Neuhalfen and Ralph Newell as both were based on sound methods and industry standards. The court found the opinions of Victor DeClercq as to the lack of electrical arcing evidence and the significance of the absence of such evidence admissible. Experts: Andrew Neuhalfen (fire origin expert), Ralph Newell (fire origin expert), Victor DeClerq (electrical engineering), Eric Dahlquist (automotive consumer expectations), James Valentour (toxicologist), John Habberstad (engineering), Gray Broughton (vocation and rehabilitation).

Key Language

- "Newell may also testify about his fire vector analysis as that methodology is recognized in NFPA 921 §15.2.3. What Newell may not do, however, is engage in prejudicial speculation as to the ignition source of the fire which lacks any basis in fact... Tunnell complains that Newell made no pictures or notes reflecting his fire vector analysis, and questions whether he actually did the analysis. The extent to which Newell's scientific method is subject to criticism by failing to record his observations may be brought out during cross-examination and is properly a question of the weight to be given this evidence by the jury." *Tunnell*, 330 F. Supp. 2d at 742.
- "A salient problem with the Habberstad tests is that there is no empirical comparison of data from the actual and test crashes. Tunnell argues that there is no way to determine at present whether the Habberstad crash tests are substantially similar because Ford has not provided sufficient data from the restraints control module in the crashed vehicles to ascertain whether the change in velocity (Delta-V) in the crash test is the same as that in the Athey vehicle." *Id.* at 746.

Fifth Circuit

Wells v. SmithKline Beecham Corp. 601 F.3d 375 (5th Cir. 2010)

Factual Summary

Patient who incurred over \$10 million in gambling losses filed suit against the manufacturer of Requip, a drug to alleviate the symptoms of Parkinson's disease, alleging that it failed to warn him of the potential danger of pathological gambling while taking the drug. To support this claim, the plaintiff offered the testimony of three medical causation experts. Based on

literature, a single unpublished study, the manufacturer's internal data of case-specific associations, and the subsequent addition of a warning label, these experts opined that Requip can cause pathological gambling. In the district court, the defendant moved for summary judgment, arguing, in part, that this testimony did not meet *Daubert*'s admissibility requirements. The district court decided that, even if the testimony was admissible, it was not scientifically reliable evidence of causation as required by Texas tort law. The Fifth Circuit affirmed, stating that, of plaintiff's three purported experts, "[n]one did more than baldly state that Requip can cause problem gambling." Wells, 601 F.3d at 379. Upon a closer examination of their methodology, the court concluded that it was fundamentally flawed and the district court properly excluded each expert's testimony.

Key Language

- "The experts based their general causation conclusion primarily on the scientific literature, which they claim shows an association between Requip and problem gambling. The literature, though, does not provide the necessary 'scientific knowledge' upon which to base an opinion under Daubert. [One purported expert] characterized all but one of the studies as 'anecdotal evidence,' and each expert conceded that the studies were not statistically significant epidemiology. They were, in fact, case studies. Although, '[c]ase-control studies are not per se inadmissible evidence on general causation,' this court has frowned on causative conclusions bereft of statistically significant epidemiological support." Wells, 601 F.3d at 379-80 (quoting Knight v. Kirby Inland Marine, Inc., 482 F.3d 347, 352 (5th Cir. 2007)) (internal footnotes omitted).
- "[I]n addition to the literature, Wells'[] experts purport to rely on GSK's internal documentation in reaching the conclusion that Requip causes problem gambling. Specifically, GSK has, over the years and per the FDA's requirements, collected data on patients suffering increased gambling when taking Requip. This data shows a relatively high number of self-reported spikes, but mining this data is not the scientific method; rather, it is rife with bias and variability." *Id.* at 381 n.30.

Hathaway v. Bazany 507 F.3d 312 (5th Cir. 2007)

Factual Summary

A teenage driver died after being shot while speed-

ing away from a traffic stop and striking a police officer. The driver's parents filed suit against the officer and the locality, alleging civil rights violations. In response to the defendants' motion for summary judgment, the plaintiff offered an affidavit from the driver's father, a former police officer with expertise in firearms training, as an expert witness. He opined that the officer had to have been behind the vehicle when the shot was fired, because otherwise, the bullet would have entered the windshield. The district court concluded that this testimony did not possess the reliability required by Daubert and excluded it. The Fifth Circuit stated that this testimony was "little more than personal assurances" based on "a host of unsupported conjectures that falls far short of a methodology." Hathaway, 507 F.3d at 318. Accordingly, it affirmed.

Key Language

- "[The *Daubert*] factors are not mandatory or exclusive; the district court must decide whether the factors discussed in *Daubert* are appropriate, use them as a starting point, and then ascertain if other factors should be considered. But the existence of sufficient facts and a reliable methodology is in all instances mandatory. '[W]ithout more than credentials and a subjective opinion, an expert's testimony that it is so is not admissible." *Hathaway*, 507 F.3d at 318 (quoting *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 424 (5th Cir. 1987)).
- "Harry Hathaway offers little more than personal assurances based on his police experience that his conclusions are so, amply justifying the trial court's exclusion of his testimony both on the basis of insufficient factual support and lack of reliable methodology. Hathaway's qualifications as an expert arise from his career as a law enforcement officer and special expertise in firearms training. But his primary argument, that Bazany must have been behind the car when he fired his shot, is not based on any discernable training in or use of a scientific methodology suited to the reconstruction of the location of a shooter based on the trajectory of the bullet or location of a shell casing. Instead, Hathaway relies on a host of unsupported conjectures that falls far short of a methodology." Id. at 318.

Curtis v. M & S Petrol., Inc. 174 F.3d 661 (5th Cir. 1999)

Factual Summary

The plaintiffs alleged that exposure to excessive amounts of benzene while they were employed as re-

finery workers caused various health symptoms. The plaintiffs sought to introduce the testimony of Dr. Frank Stevens regarding medical causation. The district court excluded Dr. Stevens' testimony, finding that his ultimate conclusion that the plaintiffs' symptoms were caused by their exposure to benzene was not reliable because the plaintiffs failed to demonstrate with sufficient certainty the amount of benzene to which they were exposed. The Fifth Circuit reversed the district court's ruling as an abuse of discretion, finding that Dr. Stevens had found on a reliable basis that the plaintiffs were exposed to benzene at levels several hundred times higher than the permissible exposure level. Expert: Frank Stevens (industrial hygienist, on exposure and causation).

Key Language

- Dr. Stevens testified that the symptoms experienced by the refinery workers were all indications of exposure to benzene at levels of at least 200–300 ppm. *Curtis*, 174 F.3d at 671.
- Dr. Stevens relied upon the results of the Draeger tube tests performed by the refinery workers. The tubes used were designed to measure a maximum of 10 ppm based on 20 pumps. Because they were only pumped twice before becoming saturated, measuring the maximum of 10 ppm, Dr. Stevens calculated that the refinery workers were exposed to at least 100 ppm. *Id.*
- Dr. Stevens relied upon the work practices at the refinery and found that the various functions performed and the design of the refinery made exposure to high levels of benzene likely. *Id.*
- "The evidence amply supports Dr. Stevens's finding that the refinery workers were exposed to benzene at levels several hundred times the permissible exposure level of 1 ppm.... [He] had 'more than a paucity of facts' about the level of benzene to which the refinery workers were exposed." *Id.* at 672.

Black v. Food Lion, Inc. 171 F.3d 308 (5th Cir. 1999)

Factual Summary

The plaintiff slipped on the floor in the defendant's supermarket. Thereafter, she was diagnosed as having fibromyalgia syndrome. The plaintiff sought to admit testimony from her diagnosing doctor, Dr. Mary Reyna, indicating that the fall caused her fibromyalgia. Dr. Reyna specialized in treating patients with persistent pain and theorized that the fall caused physical trauma to the plaintiff, resulting in "hormonal changes" that caused fibromyalgia. Because Reyna's theory had not been verified by testing, failed to gain acceptance in the

medical profession, and had no known potential rate of error, the Fifth Circuit reversed the trial court's admission of her testimony because it was not based on a reliable methodology. Expert: Dr. Mary Reyna (physician specializing in pain management, on causation).

Key Language

- "Dr. Reyna's theory—that the fall caused trauma that caused hormonal damage leading to fibromyalgia—fail[s] all three tests. First, Dr. Reyna's theory has not, according to the evidence at trial, been verified by testing and, thus, has not been peer reviewed. In fact, Dr. Reyna acknowledges that fibromyalgia has no known etiology (*i.e.*, medical science does not know if the cause of the condition is muscle, nerve, or hormone damage)." *Black*, 171 F.3d at 313. "If medical science does not know the cause, then Dr. Reyna's 'theory' of causation, to the extent it is a theory, is isolated and unsubstantiated." *Id*.
- "It also follows from the scientific literature that Dr. Reyna's theory has failed to gain acceptance within the medical profession. Experts in the field conclude that the ultimate cause of fibromyalgia cannot be known, and only an educated guess can be made based on the patient's history." *Id.* "Finally, Dr. Reyna's theory of causation... also has no known potential rate of error." *Id.*

Watkins v. Telsmith, Inc. 121 F.3d 984 (5th Cir. 1997)

Factual Summary

A widow brought suit after her husband was killed when the wire rope supporting a conveyor manufactured by the defendant's predecessor-in-interest snapped, and the conveyor fell on her husband. The plaintiff alleged that the conveyor embodied an unreasonably dangerous design because the conveyor arm was supported by only one wire rope. The plaintiff offered the expert testimony of Marcus Dean Williams, a professional engineer with a background in civil engineering, to assert that the conveyor was unsafe and that alternative designs were feasible. The district court excluded Williams's testimony on the grounds that he failed to test any of his proposed alternatives. The Fifth Circuit affirmed. Expert: Marcus Dean Williams (civil engineer, on alternative design).

Key Language

"First, the proper methodology for proposing alternative designs includes more than just conceptualizing possibilities. The district court appropriately

- noted the lack of testing of any of the proposed alternatives." *Watkins*, 121 F.3d at 992.
- "Second, the fact that Williams had 'seen' conveyors with hydraulic cylinders, outriggers, and stop-plates, without more information regarding the types of conveyors and their intended functions, does not save his testimony from its lack of empirical support. [He] did not investigate designs of other conveyors available...." *Id*.
- "Thus, the district court did not err in concluding that Williams made his assessment of unreasonable dangerousness and proposed his alternative designs 'without... any scientific approach to the proposition at all." *Id.* at 992–93.

Imperial Trading Co. v. Travelers Prop. Cas. Co. of Am. 654 F. Supp. 2d 518 (E.D. La. 2009)

Factual Summary

The owners and lessees of commercial properties that were damaged during Hurricane Katrina filed suit against their insurer, alleging that it failed to participate in the adjustment process in good faith. To support their claims, the plaintiffs offered the testimony of Peter Knowe, who was proffered as an expert in industry standards and practices, specifically, the issue of bad faith. The defendant moved to exclude his testimony. The district court granted this motion, stating that Knowe's report "reads more like a closing statement delivered by a trial attorney than a technical analysis provided by an expert witness," particularly since most of his conclusions were "unmoored to any analysis or method." *Imperial Trading Co.*, 654 F. Supp. 2d at 521.

Key Language

• "[T]he Knowe Report provides no indication as to how Mr. Knowe's methods or analysis led to the factual conclusions he provides. As such, his opinion is little more than an *ipse dixit* directive to the jury to believe the plaintiffs' evidence. This analysis is representative of the report as a whole. The report contains virtually no citations. It provides no basis for many observations and conclusions. The report provides numerous opinions as to the scope of the policy's coverage, but at no point does Mr. Knowe explain his analysis of the policy. In fact, the policy language is not cited in the report at all. Mr. Knowe's report does not explain how numerous, repeated conclusions about defendant's conduct—that it was 'dishonest,' 'deliberate,' 'arbitrary and capricious,' 'unreasonable,' 'unfair,' 'in

bad faith'—were reached. In short, it is difficult to discern any method at work in much of the analysis, and the Court cannot determine how the conclusions stated are the result of Mr. Knowe's expertise. While it is clear that Mr. Knowe has considerable experience in the insurance industry, his process for coming to conclusions is opaque." *Imperial Trading Co.*, 654 F. Supp. 2d at 522.

King v. Synthes (U.S.A.) 532 F. Supp. 2d 828 (S.D. Miss. 2006)

Factual Summary

After a tree fell on his arm, a patient had a rod implanted in it. Several years later, he brought an action against the rod's manufacturer, alleging that it broke, requiring him to undergo additional surgeries. The only expert testimony proffered by the plaintiff was from Edward W. Reese, Ph.D., who professed to be an expert in the Food and Drug Administration's rules and regulations. After relying on documents primarily given to him by the plaintiff's counsel, Dr. Reese opined that a defect likely caused the plaintiff's injuries, the rod was mislabeled, it had not been adequately tested, and the manufacturer failed to comply with certain FDA regulations. The defendant filed a motion to exclude this testimony. The court granted this motion, concluding that it was "unpersuaded that Dr. Reese's testimony is based upon the appropriate scientific methodology as Daubert commands." King, 532 F. Supp. 2d at 836.

Key Language

- "The party sponsoring the expert testimony has the burden of showing that the expert's findings and conclusions are based upon the scientific method and, therefore, are reliable. 'This requires some objective, independent validation of the expert's methodology. The expert's assurances that he has utilized generally accepted scientific methodology is insufficient." King, 532 F. Supp. 2d at 832 (quoting Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998)).
- "This court is not persuaded that Reese's methodology in reaching his conclusions passes the *Daubert* test.... Dr. Reese made only a cursory inspection of the Synthes Rod explanted from Mr. King... Dr. Reese did not analyze nor test the design of the Synthes Rod, nor did he compare the design features of the Synthes Rod with other intra-medullary rod devices. Additionally, Dr. Reese testified that [he] has requested on several occasions that Synthes provide him information for him to review; yet, he already has rendered a 'professional opinion' on whether the

Synthes Rod complies with FDA rules and regulations." *Id.* at 832–33.

Apex Eyewear, Inc. v. Elite Optik, Inc. 2002 WL 1751381 (N.D. Tex. Apr. 4, 2002)

Factual Summary

The plaintiff brought a patent infringement action and offered the testimony of its expert, David Chao. Chao's testimony related to (1) how one with ordinary skill in the art would interpret the terms of the subject patent and (2) whether the subject patent had been infringed. The plaintiff also offered the testimony of Dr. Arun Kumar regarding whether the allegedly infringing products auxiliary frames touched the primary frames as described in the claim limitations of the subject patent. The court held that the methodology relied on by each expert, although not scientific, was reliable, and thus found the testimony of both experts to be admissible. Experts: David Chao (co-inventor of design similar to litigated patent); Dr. Arun Kumar (unspecified, on prior art).

Key Language

- "[D. Chao] provided his opinion as to the meaning of certain patent terms 'based on his knowledge and experience in the eyewear industry and of eyewear design.' The court considers this methodology—that of applying specialized knowledge and experience to the language and prosecution history of a specific patent in order to determine the meaning of its terms—to be reliable for determining how one with ordinary skill in the art would interpret the claim language of the §207 patent. Moreover, because 'testimony on the ultimate issue of infringement is permissible in patent cases,' the same methodology, supplemented by an examination of a number of [the relevant] models, is admissible and reliable for determining whether those models infringe the \$207 patent." Aspex Eyewear, Inc., 2002 WL 1751381, at *31.
- Dr. Kumar's assistant bought each of [Defendant's] tested products and a random sample of six different products to ensure that different models were available. "The court holds that this is an appropriate and reliable methodology to determine whether a product infringes the \$207 patent, because it involved a direct retail purchase without intervening use of the eyewear by others, and because it was performed randomly. *Id.* at *32.

Lassiegne v. Taco Bell Corp. 202 F. Supp. 2d 512 (E.D. La. 2002)

Factual Summary

The plaintiff sued, alleging he suffered from numerous health problems, including impotency, migraine headaches, and post-traumatic stress disorder, as a result of choking on a chicken bone while eating the defendant's food. He sought to admit the testimony of three experts, including Dr. Susan McSherry, a urologist and Dr. Steven Atkins, a neurologist. The court excluded the doctors' testimony on the grounds that their testimony did not have a scientific basis sufficient to support a conclusion regarding causation. Experts: Susan McSherry (urologist); Steven Atkins (neurologist) on causation and injury.

Key Language

- "Dr. McSherry testified that the 'process of elimination' methodology to determine whether the cause of erectile dysfunction is neurogenic is a theory that has been generally accepted by the urological scientific community. She testified that the theory has been subjected to peer review and publication." *Lassiegne*, 202 F. Supp. 2d at 517.
- "The Court finds that although Dr. McSherry may have followed an accepted methodology in diagnosing Lassiegne with erectile dysfunction, her ultimate conclusion that the choking incident caused erectile dysfunction is unreliable. Dr. McSherry presents no scientific basis, no 'specific train of medical evidence' to link Mr. Lassiegne's choking incident to his erectile dysfunction." *Id*.
- As stated in *Black v. Food Lion*, 171 F.3d 308, 314 (5th Cir. 1999), "the use of a general methodology cannot vindicate a conclusion for which there is no underlying medical support." *Id*.
- Dr. Atkin's testimony that the choking incident caused the plaintiff's migraines suffered the same flaws as Dr. McSherry's testimony. "To be helpful on the issue of medical causation, Dr. Atkins must do more than diagnose plaintiff with migraine headaches or establish that deprivation of oxygen to the brain can cause migraine headaches. Rather, he must provide a reliable causative link...." *Id.* at 518. Because Dr. Atkins offered no scientific support for a general theory that loss of oxygen for any *amount of time* would cause brain damage sufficient to result in migraine headaches, the court excluded his testimony as unreliable.

Miller v. Burlington N. Santa Fe Ry. Co. 2001 WL 1326552 (N.D. Tex. Oct. 16, 2001)

Factual Summary

A railroad engineer brought suit against the owners of a vehicle that collided with his train and sought damages for lost earnings that resulted from injuries he allegedly suffered in the collision. The defendants filed a *Daubert* motion challenging the testimony of the plaintiff's economic expert, Jeffrey B. Opp. Because Opp's methodology applied basic mathematics, the court held that his proffered testimony met the reliability prong of the *Daubert* standard. Expert: Jeffrey B. Opp (economist, on lost earnings).

- Opp's opinion was based on the mathematical differential between the amount of earnings plaintiff experienced in the past and reasonably could anticipate in the future had he not been injured and those same past and future earnings he experienced and reasonably could anticipate earning in the future in his injured state. To arrive at the differential, Opp took known data, added in the calculated value of the fringe benefits, deducted the federal income taxes reported and/or paid, backed out certain expenses and retirement payments, then arrived at the "net" historical railroad earnings. "The mathematical functions used to arrive at such historical figures were addition, subtraction and multiplication, all grade school skills. From the baseline of that 'historical' data, Opp projected the figures into the future using a commonly recognized mathematical principal known as 'extrapolation.' This function does not presume or assume a straight line ('linear') relationship between past occurrences and future events, an assumption that may be challenged on cross-examination, but is fair to assume and is not junk science." Miller, 2001 WL 1326552, at *2.
- Opp used "set theory" to project Plaintiff's earnings into the future by assuming that Plaintiff was a member of a class of similarly situated railroad employees (the "set") and projected that Plaintiff's future earnings would be affected by the same factors that did affect the set members in the past and would affect the members in the future. "The use of a set to project the effects of certain assumed events is recognized methodology for predicting effects on individual members of the set." *Id*.
- "[Defendants] complained about Opp's extensive use of annualizations in his calculations of earnings differentials. Annualizations of fiscal data are common and are as accurate as using averages or calculating means. Again, fodder for cross-examination but not exclusion." *Id.* at *2–3.

 "The methodology is not proper subject of peer review. The bachelor's degree in economics which Opp holds reflects the degree of mastery of basic mathematical, statistical and language skills necessary to perform the compilations, calculations and formulae sections used by Opp in his analysis and in making his report. Brain surgery it ain't. And Einstein did not have a degree in nuclear physics either. Opp's proffered testimony meets the reliability prong of Daubert." Id. at *3.

Practice Tip

Another good example of why vocational economics are difficult to challenge. Rather than attacking the methodology of calculations (open for cross-examination), focus on the assumptions and testimony that underlie the differential foundation the economist is calculating.

Iwanaga v. Daihatsu Am., Inc. 2001 WL 1910564 (W.D. Tex. Oct. 19, 2001)

Factual Summary

The plaintiff brought a products liability action alleging the defendant manufactured a vehicle with design defects in its driver's seat system, which caused the plaintiff's injuries during an accident. Plaintiff sought to introduce expert testimony of Jahan Eftekhar, Ph.D., regarding the design defects of the driver' seat system in the vehicle, and of John J. Smith, regarding the biochemical issues surrounding the plaintiff's back injuries. Despite objections, the district court adopted the magistrate judge's findings that both experts applied their engineering knowledge and expertise to the specific facts of the case and there was no evidence that their methodologies were unsound or unreliable. (However, portions of Eftekhar's testimony and most of Smith's testimony were excluded on spoliation of evidence grounds.) Experts: Jahan Eftkehar (mechanical engineer); John J. Smith (electrical engineer with training in reconstruction and biomechanics, on design defect).

Key Language

- "Mr. Eftekhar applied his engineering knowledge and experience to the specific facts of the case as elicited from his investigation of those witnesses who were present at the scene of the accident... He performed seat loading tests and used standard scientific and mathematical formulas to develop his final opinions as to how the accident occurred, the dynamics of the accident and the speed of vehicle." Iwanaga, 2001 WL 1910564, at *9.
- "He visited the accident site on at least three occasions

- to gage [sic] the accurate travel path of the vehicle, conducted two visual inspections of the 1990 Rocky involved in the accident, and performed seat loading tests on exemplary seat systems as well as on the actual seat." Id. at *10.
- "Mr. Eftekhar further arrived at the conclusion that in all reasonable probability, the absence of the C-shaped metal bar would have prevented the type of injuries suffered by [the plaintiff]." Id. at *9.
- · In examining other comparable vehicles, he discovered that none contained the C-shaped metal bar and that none placed a hydraulic jack under the seat, leading him to conclude that safer alternative seat designs were available at the time and that placement of the jack under the seat was unreasonably dangerous and unnecessary. Id. at *9-10.
- "There is no evidence before me that Eftekhar's methodology in forming what became his 'final' opinion... is unsound or unreliable." *Id.* at *10.
- "Mr. Smith testified that he received research materials, photographic evidence, test results and reports prepared by Eftekhar, medical information from [Plaintiff's] physicians on the extent of his lower back injuries, and the accident report prepared by State Trooper Gilliam. He also applied mathematical formulas and Newton's law of motion to assess the speed of the vehicle and the energy transmitted from the C-shaped bar to [Plaintiff's] spine." *Id.* at *11. He visited the site of the accident and conducted a visual inspection of the same. He also examined the 1990 Rocky and inspected its driver seat system.

Vienne v. Am. Honda Motor Co. 2001 WL 43598 (E.D. La. Jan. 16, 2001)

Factual Summary

The plaintiff brought suit against the manufacturers of a three-wheeled vehicle that rolled over and allegedly caused him severe head injuries. The defendants sought to exclude the testimony of Dr. Robert R. Wright, the expert that the plaintiff designated to testify about the three-wheeler's allegedly defective design, the inadequacy of the defendants' warning, their advertising practices, and accident reconstruction. With respect to the expert's testimony regarding accident reconstruction, the defendants argued that the methodology underlying Wright's testimony was not scientifically valid. The court disagreed and held that, because his opinions were based on the laws of physics and routine calculations that have been tested and peer reviewed, the methodology was reliable and his testimony would be allowed. Expert: Robert Wright (practical experience

with vehicles involved in case, academic background in engineering and mathematics).

Key Language

• "Wright photographed the accident scene, studied the three-wheeler's condition, tested its throttle, reviewed the accident report prepared by the sheriff's department, measured the accident site, examined the dynamics of the vehicle, and analyzed the accident scenario. The Court finds that the [sic] Wright's opinions are based on the laws of physics and on routine calculations which have been tested, peer reviewed, and regularly relied on by engineers in accident reconstruction." Vienne, 2001 WL 43598, at *4.

United States v. Potts 2000 WL 943219 (E.D. La. July 2000)

Factual Summary

The government filed a Notice of Intent to Utilize Narcotics Expert Witness in Drug Trafficking in a criminal trial. It sought to prove that the tractor-trailer that the defendant was driving, which had 150 kilograms of cocaine stored in it, and the route that he was traveling, evidenced his intent to carry and distribute the drugs. The government intended to call Chris Ortiz, a DEA Intelligence Analyst, to testify about the source, value, and quantity of the drugs to assist the jury in determining whether they were for personal use or distribution. The defendant objected on grounds that testimony was irrelevant and unreliable. The court found that Ortiz's methodology was reliable so as to pass the *Daubert* test. Expert: Chris Ortiz (DEA Intelligence Analyst specializing in drug trafficking, on value of narcotics).

Key Language

- "Mr. Ortiz's methodology for determining the monetary value of the cocaine seized from the defendant is detailed in the graph he prepared for trial. The graph reflects that Mr. Ortiz first breaks down the amount of cocaine seized into kilogram, pound, ounce, and gram weights. [Based on his experience investigating the illegal distribution of narcotics,] he then uses retail prices in effect at the time the drugs were seized to assign values to each weight, taking into account the purity level of the drugs. This calculation results in a differential cost assessment of the total amount of drugs seized, based upon the dosage size." *Potts*, 2000 WL 943219, at *3.
- "The court finds that Mr. Ortiz's methodology is reasonable and reliable. The other *Daubert* factors are inapplicable to this case." *Id.*

United States v. Carroll 2000 WL 45870 (E.D. La. Jan. 20, 2000)

Factual Summary

The defendants were indicted on charges of conspiring to possess cocaine with intent to distribute. Prosecution sought to introduce a "drug ledger" that allegedly detailed the narcotics transactions that constituted the overall drug conspiracy. The defendants moved for a pretrial evidentiary hearing to ensure the reliability of FBI agent Dan Clouse's expert testimony regarding the function and meaning of the notebook. The court held that because the government had made a sufficient showing of the reliability of Clouse's methodology in showing that the ledger was for drug activity and not legitimate business activity, and the other Daubert factors were not applicable, a Daubert hearing was not necessary and the testimony was admissible. Expert: Dan Clouse (FBI Agent specializing in drug trafficking, on drug dealing practices).

Key Language

• A detailed look at the methodology Clouse employs indicates: "Clouse [] examines the records to see if they are records of obviously legitimate activity, such as household budgets or official score cards. He then examines the records for indicia of legitimate business records, which involves analyzing a number of factors. Finally, he applies his experience with such records and his specialized knowledge of drug terminology and drug transactions to look for characteristics of an illegitimate drug business. The numerous cases where expert testimony of this nature has been admitted indicate that Clouse's methodology is generally accepted by other law enforcement experts in his field." *Carroll*, 2000 WL 45870, at *8.

In re Craig's Stores of Tex., Inc. 247 B.R. 652 (S.D. Tex. 2000)

Factual Summary

Debtor Craig's Stores of Texas contracted with the Bank of Louisiana to administer its private-label credit cards and to buy its accounts receivable. After the bank-ruptcy, the debtor brought a breach of contract claim against the bank, alleging the bank had mishandled the credit accounts and committed errors that created excessive charge-backs of the accounts and eventual closure of the debtor's stores. The debtor offered the testimony of William Bloom regarding the bank's handling of the accounts. The district court found Bloom's methodology for evaluating the bank's handling of

the accounts unreliable because his evaluations of the bank's performance were subjective and could not be verified. Moreover, other industry experts had never used his methodology to determine negligence. Expert: William Bloom (credit card management).

Key Language

- "Instead of gathering independent evidence, Bloom subjectively evaluated the bank's performance based on narratives written by Craig's president. His conclusions could not be verified because they were predicated on the subjective evaluations he made. No standard that could be tested was articulated." In re Craig's Stores of Tex., Inc., 247 B.R. at 656.
- Before this case, other industry experts had never used Bloom's methodology to determine negligence. Id.

Nugent v. Hercules Offshore Corp. 2000 WL 381925 (E.D. La. Apr. 14, 2000)

Factual Summary

The plaintiff was injured after falling from offshore drilling rig as a result of an allegedly faulty safety lanyard. The defendant, Dalloz, sought to preclude testimony of the plaintiff's expert, Dr. Mehdy Sabbaghian, who practiced in the field of mechanical engineering, and co-defendant's expert, Dr. John Jacobus, who had professional experience in failure analysis and consulting on products liability and stress analysis of polymers. The court found that the methodology and testing that Dr. Jacobus relied upon in forming his opinion were sufficiently reliable to meet the first prong of Daubert, particularly where it had been subjected to peer review and publication. To the contrary, Dr. Sabbaghian's opinion did not identify the methodology he used to reach his conclusions, nor did he demonstrate how he used his mechanical engineering expertise in reaching his conclusions. Accordingly, the court granted the defendant's motion in limine to preclude the testimony of Dr. Sabbaghian, but denied its motion in limine to preclude the testimony of Dr. Jacobus. Experts: Mehdy Sabbaghian (mechanical engineer); John Jacobus (chemist) on product defect.

Key Language

- In examining the reliability of the methodology Dr. Jacobus used to analyze how the lanyard failed, the court noted that "Dr. Jacobus initially inspected, photographed, and documented noteworthy features of the lanyard." Nugent, 2000 WL 381925, at *4.
- He also participated with the plaintiff's and co-

- defendant's expert in joint inspections and destructive testing of the lanyard,... developing the test protocol, which consisted of visual inspection, measurements, documentation and microscopic examination. Id.
- The experts' destructive testing involved "photographing the lanyard, cutting the failed end, and examining the cut section with optical and scanning electron microscopy and scanning electron microscope/energy dispersive x-ray (SEM-EDX) analysis." Id.
- "Dr. Jacobus's methodology and testing of the lanyard are sufficiently reliable to meet the first Daubert factor. Dr. Jacobus's use of SEM-EDX analysis has been subjected to peer review and publication. Further, there is no evidence that Dr. Jacobus's theories are radical, untested, or not generally accepted in the chemistry community. Dr. Jacobus's expert testimony therefore meets Daubert's reliability prong." Id. at *5.

Garcia v. Columbia Med. Ctr. 996 F. Supp. 617 (E.D. Tex. 1998)

Factual Summary

The family of a deceased patient brought a medical malpractice action against the hospital where the patient was being treated, as well as the hospital's medical staff. The plaintiffs sought to offer expert testimony of several witnesses, including Daniel J. Slottje, an economic expert, and Mark Siegler, a physician. The court held that Slottje's method of calculating the decedent's future lost earning's based upon his worklife probability was an accepted practice, as was Siegler's formation of his opinion about the ethical duties that a health care provider owes based upon his years of experience and the depositions of the physicians and nurses who were present at the time of the decedent's alleged injuries. Accordingly, the court denied the defendant's motion to exclude these experts' testimony. Experts: Daniel J. Slottje (economist, on lost earnings); Mark Siegler (physician, testifying regarding ethical duties owed by health care provider to patient).

Key Language

• "Here, the methods and principles utilized by Slottje in reaching his opinions certainly have a sound basis in the field of economics. It is a commonly accepted practice in the field of economics to calculate future lost earnings based upon a worker's worklife probability and then adjust these figures for growth and inflation. The question of whether Slottje's opinions are accurate in light of his use of the United States figures for worklife expectancy [as opposed to Mex-

- ico figures] is a question that goes to the weight, not the admissibility, of this evidence." *Garcia*, 996 F. Supp. at 623.
- "The fact that Siegler's opinions are not based upon independent 'tests' or some type of 'scientific' study does not render them inadmissible under Rule 702 or *Daubert*. Siegler's opinions are based upon his own experience as a doctor and upon the sworn testimony of several of the plaintiffs, as well as the doctors and nurses who were present at the time of [decedent's] alleged injuries. Therefore, Siegler's opinions are based upon a sound and reliable foundation and may assist the jury in determining whether the defendants caused the plaintiffs' alleged injuries." *Id.* at 627.

Bennett v. PRC Pub. Sector, Inc. 931 F. Supp. 484 (S.D. Tex. 1996)

Factual Summary

Several police dispatchers brought suit alleging the defendant distributed a computer-aided dispatch system that was defectively designed and unreasonably dangerous, which caused their repetitive stress injuries. The court held that the plaintiffs' expert's methodology was not reliable because he failed to establish an empirical foundation. Expert: Lawrence John Henry Schulze (ergonomics expert, on design defect and causation).

Key Language

- "As to Dr. Schulze's Opinion A, on the alleged causes of the Plaintiffs' injuries, and Opinion C, on the alleged defective design of the workstations, Dr. Schulze's methodology was inadequate. It consisted of only: a superficial review of the ten Plaintiffs' medical and workers compensation records related to the injuries in issues; some measurements of the offending equipment (with uncertainty as to which chairs were used by the Plaintiffs); and a brief visual observation of certain workers performing the jobs in issue. This methodology is not consistent with the methodologies described by the authors and experts whom Dr. Schulze identifies as key authorities in the field." *Bennett*, 931 F. Supp. at 494.
- "The Court finds on the record submitted that the methodology and scientific basis are lacking for Dr. Schulze's causation opinion." *Id.* at 497.
- "[He] did not analyze the degree of force involved in the keystroke repetitions that would be problematic or would affect the incidence of CTS or other similar injuries...." *Id.* at 497–98. "[He] did no evaluation of the frequency of the necessary typing or its

- intensity or need for speed." *Id.* at 498. "By contrast, the literature on which he relies suggest that repetitive keystroking is a major work-related problem, but indicates that quantitative tests are feasible. Nothing submitted by Dr. Schulze quantifies the problem with respect to these Plaintiffs, or attempts even to address this issue." *Id.*
- "Finally, while 'general acceptance' of a scientific theory is no longer a requirement for 'reliability' and thus admissibility, the Court may consider the scientific community's reaction as one aspect of the reliability analysis. No authoritative literature was produced to the Court showing general acceptance in the scientific community of Dr. Schulze's view that 'the proximal' or 'the root' cause of Plaintiffs' injuries could be determined with the minimal information on which Dr. Schulze relied." *Id.* at 499.

Sixth Circuit

United States v. Martinez 588 F.3d 301 (6th Cir. 2009)

Factual Summary

The defendant, an anesthesiologist, was convicted for unlawful distribution of a controlled substance and various fraud offenses, including health care fraud resulting in the death of a patient, for his role in the events surrounding the deaths of two patients. To prove that the defendant's actions caused the death of his patients, the government offered the testimony of Dr. Theodore Parran, a specialist in pain management and treatment of addiction. Dr. Parran reviewed the patients the defendant saw and testified that the defendant ignored "'red flags' indicating that a patient's drug use 'was out of control." Martinez, 588 F.3d at 308. After he was convicted at trial, the defendant appealed, claiming, inter alia, that Dr. Parran's expert testimony was inadmissible because it was mere speculation. The Sixth Circuit rejected this claim and affirmed.

- The Sixth Circuit reiterated *Daubert*'s statement that courts should focus on principles and methodology, rather than conclusions, but noted that courts "must confirm that the 'factual underpinnings of the expert's opinions were sound." *Martinez*, 588 F.3d at 323 (quoting *Greenwell v. Boatwright*, 184 F.3d 492, 498 (6th Cir. 1999)).
- The court concluded that Dr. Parran's testimony was properly admitted because "it is more than the sort of 'unsupported speculation' that is prohibited, as

it was based on [his] examination of the toxicology reports and the patients' files." Id. at 324.

Best v. Lowe's Home Ctrs., Inc. 563 F.3d 517 (6th Cir. 2009)

Factual Summary

A customer brought suit against a home improvement store after pool chemicals spilled onto his face and clothing while shopping in the store, allegedly causing him to suffer from permanent anosmia, the loss of his sense to smell. To prove the causal link between the chemical spill and his injuries, the plaintiff offered the testimony of Dr. Francisco Moreno. Dr. Moreno reached this conclusion using the methodology of differential diagnosis. The district court excluded Dr. Moreno's testimony, concluding that his methodology was nothing more than "unscientific speculation." The Sixth Circuit reversed, adopting a reformulated test for district courts to apply when evaluating the reliability of differential diagnosis testimony. Because the court concluded that its "function is not to determine whether the opinion is airtight," but rather to "decide whether Dr. Moreno performed his duties as a diagnosing physician to the professional level expected in his field," it held that "Dr. Moreno's differential-diagnosis testimony meets the threshold level of admissibility under Daubert." Best, 563 F.3d at 183-84.

Key Language

- "This court recognizes differential diagnosis as 'an appropriate method for making a determination of causation for an individual instance of disease.'... Differential diagnosis is considered to be 'a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." Best, 563 F.3d at 178 (quoting Hardyman v. Norfolk & W. Ry. Co., 243 F.3d 255, 260 (6th Cir. 2001)).
- "We hereby adopt the following differentialdiagnosis test, adapted from the Third Circuit's well-reasoned opinion: A medical-causation opinion in the form of a doctor's differential diagnosis is reliable and admissible where the doctor (1) objectively ascertains, to the extent possible, the nature of the patient's injury,..., (2) 'rules in' one or more causes of the injury using a valid methodology, and (3) engages in 'standard diagnostic techniques by which doctors normally rule out alternative causes' to reach a conclusion as to which cause is most likely." Id. at 179 (quoting In re Paoli Railroad Yard PCB Litig., 35 F.3d 717, 760, 762 (3d Cir. 1994)).

- "In connection with the third 'rules out' prong, if the doctor 'engage[s] in very few standard diagnostic techniques by which doctors normally rule out alternative causes,' the doctor must offer a 'good explanation as to why his or her conclusion remain[s] reliable.' Similarly, the doctor must provide a reasonable explanation as to why 'he or she has concluded that [any alternative cause suggested by the defense] was not the sole cause." Id. (quoting In re Paoli Railroad Yard PCB Litig., 35 F.3d at 758 n.27, 760) (alterations in original).
- "[D]octors need not rule out every conceivable cause in order for their differential-diagnosis-based opinions to be admissible." Id. at 181.
- "Admissibility under Rule 702 does not require perfect methodology." Id.

Johnson v. Manitowoc Boom Trucks, Inc. 484 F.3d 426 (6th Cir. 2007)

Factual Summary

A construction worker brought a products liability action against a crane manufacturer after the truckmounted crane in which he was working tipped over, severely injuring him. To support this claim, the plaintiff offered the testimony of Gary Friend, a professional engineer. Friend opined that the crane had a design defect because it lacked an interlocking system to prevent operation of the crane when it was not on firm ground. To reach this opinion, Friend reviewed case-specific documents such as deposition testimony and discovery responses, as well as brochures, owner's manuals, and industry standards. He also personally inspected and photographed the subject crane. After the manufacturer challenged this methodology, the magistrate judge granted its motion to exclude, concluding that the Daubert factors indicated that Friend's testimony lacked a reliable foundation. The Sixth Circuit affirmed.

- After noting the importance of testing alternative designs, the court stated that if an expert was unable to test his or her theory, "[o]ne way to overcome the testing requirement might be to show that the expert has significant technical expertise in the specific area in which he is suggesting an alternative design." Johnson, 484 F.3d at 431.
- "[I]t also seems reasonable for a judge to have shut the gate on Friend because he had made no attempt whatsoever to test the interlock system in the larger machine. The magistrate judge might have abused her discretion had Friend been particularly experi-

enced in the area of truck outriggers, or cranes, or the like, but the record indicates that he is not. Friend's self-serving testimony that he is qualified to render an opinion on the design of 'almost any machine' undercuts any claims of specific expertise that he might hope to make. Friend may well be a fine engineer, but he is clearly a generalist." *Id.* at 432.

- "To decide the case, a jury would have to be presented with evidence of whether the Asplundh interlocking system could easily have been fitted onto the Manitowoc 2592 when it was produced and sold to buyers in 1999, and whether such alteration would negatively have affected the truck's safety or performance. Should a one-page diagram that is nothing more than an engineer's version of cut-and-paste suffice as such evidence? Of course not." *Id*.
- "[A]n expert who testifies based on research he has conducted independent of the litigation 'provides important, objective proof that the research comports with the dictates of good science.' However, if a proposed expert is a 'quintessential expert for hire,' then it seems well within a trial judge's discretion to apply the *Daubert* factors with greater rigor, as the magistrate judge seems to have done in this case." *Id.* at 435 (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995)).
- "The most obvious cure would have been for Friend to have produced at least *some* empirical testing data on his proposed alternative design. This he entirely failed to do. Another cure would have been for [the plaintiff] to have found someone with expertise more directly related to the large truck and/or truck crane industry. Such an expert might have been spared the *Daubert* testing factor.... And such an expert would probably look much less like the generalist 'expert for hire' epitomized by Friend." *Id.* at 436.

Mike's Train House, Inc. v. Lionel, L.L.C. 472 F.3d 398 (6th Cir. 2006)

Factual Summary

A model train distributor filed suit against a competitor for misappropriation of trade secrets and unjust enrichment. The plaintiff offered testimony from Dr. Jeffery L. Stein, a mechanical engineering professor, who testified that the defendant's design drawings were copies of the plaintiff's. To reach this conclusion, Stein examined sets of drawings from both companies for ten different train models. Then, using twenty-one self-selected criteria, such as the title of the drawing and its part number, he scored each drawing based on whether there was no association or a high degree of

similarity. Stein concluded that roughly fifty-five percent of the drawings were copies and that the overlap would not occur if the defendant worked independently. The defendant challenged Stein's testimony as unreliable. The district court rejected this challenge and permitted Stein to testify without making any specific findings as to the reliability of his testimony. After a jury returned a verdict in favor of the plaintiff, the defendant appealed, arguing, inter alia, that the district court should have excluded Stein's testimony. The Sixth Circuit agreed. Specifically, the court held that the district court abused its discretion because Stein's methodology was novel, self-created for litigation, and relied on self-selected and arbitrarily-weighed factors that ignored the realities of industry practice. Accordingly, it reversed the district court's ruling.

Key Language

- "Although it is true that 'in some instances well-grounded but innovative theories will not have been published,' and that '[s]ome propositions... are too particular, too new, or of too limited interest to be published,' the novelty of a theory does not shield an expert's testimony from judicial scrutiny." Mike's Train House, Inc., 472 F.3d at 407 (quoting Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 593 (1993)).
- "Our conclusion is also compelled by the clear evidence that Stein lacked a rudimentary understanding of the Korean model-train design industry, and was thus unable to identify those aspects of the design drawings that might be indicative of copying. For example, one factor that Stein relied upon in evaluating the similarity between two drawings was whether the part was assigned the same number. The record clearly establishes, however, that Korean manufacturers share a common numbering system for train parts.... Similarly, Stein gave weight to the name each drawing bore.... In addition to the obvious flaw inherent in a methodology that identifies copying by looking at the names of discrete component parts, Stein's methodology reveals a lack of insight into this industry by considering the numbers assigned to each train part as evidence of copying." Id. at 408.
- "We have been suspicious of methodologies created for the purpose of litigation, because 'expert witnesses are not necessarily always unbiased scientists." *Id.* (quoting *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1352 (6th Cir. 1992)).

Rolen v. Hansen Beverage Co. 193 F. App'x 468 (6th Cir. 2006)

Factual Summary

A consumer and his wife brought suit against a juice manufacturer, alleging that he became ill after drinking its juice product. To support this claim, the plaintiffs offered the testimony of Dr. Mark Houston, an internal medicine specialist, to prove causation. The district court excluded Dr. Houston's testimony as unreliable, because he never tested any of the manufacturer's products, was unaware of its manufacturing practices, and could not explain why the plaintiff became ill less than twenty minutes after he drank the juice. The Sixth Circuit affirmed.

Key Language

- "Expert opinions based upon nothing more than the logical fallacy of post hoc ergo propter hoc typically do not pass muster under Daubert." Rolen, 193 F. App'x at 473.
- The court noted that "with no supporting reasoning or methodology," Dr. Houston's analysis was "a slender reed to grasp in attempting to show causation." Id.
- "[W]e find that the district court was within its zone of discretion in determining that—to paraphrase Joiner—too great a gap existed between the available data and Dr. Houston's opinion as to causation," which, the court noted, "appears to have been based upon the logical fallacy post hoc ergo propter hoc." Id. at 474.

Conwood Co., L.P. v. U.S. Tobacco Co. 290 F.3d 768 (6th Cir. 2002)

Factual Summary

A manufacturer of moist snuff brought suit alleging that another manufacturer had used its monopoly position to exclude competitors from the snuff market. The jury returned verdict for plaintiff. The Sixth Circuit affirmed the district court's decision to admit expert testimony on business valuation and lost profits. The expert used regression analysis to test hypothesis that the plaintiffs' growth was most suppressed in states where it had only small market share when the defendants began their anticompetitive practices. Expert: Dr. Richard Leftwich (business valuation and lost profits).

Key Language

 "Leftwich employed three methods to test Conwood's claims: regression analyses, a yardstick test and a before-and-after test. All three are generally accepted methods for proving antitrust damages." Conwood Co., 290 F.3d at 792.

Downs v. Perstorp Components, Inc. 26 F. App'x 472 (6th Cir. Jan. 4, 2002)

Factual Summary

The plaintiff brought an action to recover for neurological injuries suffered after exposure to allegedly toxic chemical called Rubiflex (epoxy used in production of foam insulation). The plaintiff's treating physician, Dr. Kaye H. Kilburn, concluded after extensive testing that Rubiflex was the cause of condition. The plaintiff offered Dr. Kilburn as causation witness in products liability action against Rubiflex manufacturer. The district court found that Dr. Kilburn's testimony was unreliable. The Sixth Circuit affirmed this exclusion. The court based its decision on the fact that the expert reached conclusion on causation before he even knew what chemical components Rublifex contained, was unable to identify any specific component as cause, never ascertained dose to which plaintiff was exposed, cited to no scientific literature in support of expert's conclusion, and conducted no study or investigation to test hypothesis that Rubiflex or any of its components could cause the plaintiff's symptoms. Experts: Dr. Kaye H. Kilburn (medical); Thomas J. Callender, M.D. (medical).

Key Language

- "After careful review of the magistrate judge's opinion and the arguments made by the parties," the court was "convinced that the magistrate judge did not abuse his discretion in excluding Dr. Kilburn's testimony because his conclusions were not based on valid scientific methodology." Downs, 26 F. App'x at 474.
- "The most obvious problem with Dr. Kilburn's methodology is that he never identified the component or components in Rubiflex that were responsible for Downs' condition." Id. at 476.
- "In essence, Dr. Kilburn's methodology primarily involved reasoning backwards from Downs' condition and, through a process of elimination, concluding that Rubiflex must have caused it.... He failed to take the necessary step of either supporting his hypothesis through reference to existing scientific literature or conducting his own tests to prove its reliability." Id.

Nelson v. Tenn. Gas Pipeline Co. 243 F.3d 244 (6th Cir.), cert. denied, 122 S. Ct. 56 (2001)

Factual Summary

Seven bellwether plaintiffs who lived, worked, or spent time near natural gas pipeline compressor station brought a class action against operator of station, and its parent company, seeking to recover for injuries allegedly caused by exposure to polychlorinated biphenyls (PCBs) contained in lubricant used at compressor. The plaintiffs offered two physician experts on medical causation: Dr. Kilburn and Dr. Hirsch. The magistrate judge excluded testimony from both physicians and awarded summary judgment to defendants. The Sixth Circuit affirmed this exclusion. Specifically, because Dr. Kilburn failed to account for confounding factors, did not establish temporal relationship between exposure and illnesses, failed to show sufficient dose to make the plaintiffs ill, and did not demonstrate general acceptance of his theories, his testimony was unreliable. Furthermore, the circuit court held that the magistrate properly gave weight to lack of peer review or publication of Dr. Kilburn's litigation study, even though Dr. Kilburn had authored and published other peer-reviewed studies. Dr. Hirsch failed to offer reliable scientific support for his conclusion that PCB exposure caused those impairments. Experts: Kaye H. Kilburn, M.D. (medical); Alan R. Hirsch, M.D. (medical).

Key Language

- "In examining the scientific validity of the methodology Kilburn used to conclude that the plaintiffs were injured as a result of exposure to PCBs, the magistrate judge focused most heavily upon Kilburn's failures to account for 'confounding factors' that could have caused similar symptoms." The circuit court agreed that, "the flaws in the methodology underlying Kilburn's opinion that PCB exposure caused the plaintiffs' impairments, as well as a lack of support for the proposition that environmental PCB exposure can cause the impairments Kilburn found in the Lobelville subjects, rendered his opinion unreliable." *Nelson*, 243 F.3d at 252.
- "A significant flaw in Kilburn's methodology [is] his cohort epidemiological study (which) seeks to demonstrate a relationship between exposure and disease by comparing those who have been exposed with those who have not. Without any factual basis from which a jury could infer that the plaintiffs were in fact exposed to PCBs... the reasoning and methodology underlying the testimony is not scientifically valid." *Id.* at 253.
- "It is the methodology by which [the expert] reached his opinion concerning causation that must be found reliable. [The expert] admitted no knowledge concerning the actual exposure of the seven plaintiffs to PCBs or the temporal relationship between their exposure and symptoms. The magistrate judge prop-

erly rejected the circular reasoning that the plaintiffs must have been exposed to the PCBs because PCBs were present in the environment and plaintiffs showed symptoms." *Id.* at 254.

United States v. Langan 263 F.3d 613 (6th Cir. 2001)

Factual Summary

The defendant was convicted of robbing two banks and of using firearms and a destructive device in committing the robberies. When shown photos, an eyewitness identified a suspect as the robber, although she saw television coverage of the suspect's arrest. The defendant moved to exclude the witness' testimony. The district court denied the motion, as well as the defendant's motion to present the testimony of David F. Ross, a psychologist at the University of Tennessee, a purported expert in eyewitness identification. The district court refused to allow Dr. Ross to testify because his proposed testimony failed to meet the requirements of Rule 702 of the Federal Rules of Evidence as interpreted by *Daubert*. The Sixth Circuit affirmed. Expert: Dr. Ross (psychologist).

Key Language

- As part of *Daubert* review, district court considering proffer of scientific expert testimony must assess whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology properly can be applied to the facts in issue. *Langan*, 263 F.3d at 613.
- The district court held that Dr. Ross's testimony concerning the transference theory was not sufficiently based on "scientific knowledge," because it failed to meet the reliability standards established by *Daubert*. Citing Dr. Ross's own 1994 article, the court noted that Dr. Ross had personally called into question when commenting that the "literature provides mixed and somewhat weak support for unconscious transference" and that the "empirical evidence for the [theory's] existence is rather meager." *Id.* at 619.
- "The district court found that Dr. Ross's methodologies were inadequate because he had never studied any victim or eyewitness of a bank robbery." *Id.*

Clay v. Ford Motor Co.

215 F.3d 663 (6th Cir.), cert. denied, 531 U.S. 1044 (2000)

Factual Summary

In action arising out of rollover accident involving sport utility vehicle (SUV) which resulted in the death of the

occupants, a jury awarded compensatory damages and prejudgment interest to estates of deceased passengers. The plaintiffs offered testimony from a mechanical engineer who reconstructed the accident and testified that the automobile design was defective. The defendant argued that the plaintiffs' expert did not inspect the vehicle, was late in visiting scene of accident, and did not test his theory that the SUV had a tendency to oversteer. The Sixth Circuit affirmed the district court's decision to admit this testimony. Specifically, it concluded that these issues went to the weight of the expert's testimony, not its admissibility. Expert: Dr. Melvin Richardson (mechanical engineering, machine design, vehicle dynamics, and accident reconstruction).

Key Language

- In cases "involving scientific opinion (*Daubert* cases) or applied scientific opinion as in matters of engineering (*Kumho* cases), it is the methodology employed by the expert, not the expert's general educational qualifications, that is in issue. Dr. Richardson's impressive academic and experiential history tells us nothing about how he did what he did to reach his conclusions in this case." *Clay*, 215 F.3d at 675.
- "While this evidence indirectly suggests that Dr. Richardson thought his methodology was reliable, it hardly suffices as evidence of reliability under *Daubert*. Nothing in this testimony touches on any of the *Daubert* factors, or any other measures of reliability, for that matter. The record is absolutely devoid of any indication that the process or methodology Dr. Richardson employed in reaching his accident reconstruction opinion was 'good science' or 'good engineering." *Id.*
- "What *Daubert* and *Kumho* require of the proponent of expert opinion is evidence that the methodology underlying the expert's conclusion is 'good science' or 'good engineering.' That means that the plaintiffs were obligated to introduce at least some evidence that Dr. Richardson's method—that is, examining depositions, police reports, photographs of the vehicle,...—is a sound engineering methodology for evaluating vehicle design." *Id.* at 676.

Pride v. BIC Corp. 218 F.3d 566 (6th Cir. 2000)

Factual Summary

A widow brought a products liability action against the marketer of fixed-flame cigarette lighter, alleging that the lighter caused husband's death. The plaintiff offered three experts: a mechanical engineer, a firefighter, and an analytical chemist. The engineer opined, based on inspection of lighter, that an exploding-lighter scenario was the most likely cause of fire, resulting from a manufacturing defect. The firefighter opined that the lighter was most likely cause of fire based on elimination of other plausible causes as well as information suggesting that fire started in victim's breast pocket. The chemist opined, based on information regarding the condition of plastic from the lighter, that the lighter exploded. The district court denied the widow's requests to tender additional expert testimony and accepted the magistrate's recommendation that all three experts be excluded. The Sixth Circuit affirmed the exclusion of this testimony. None of widow's experts conducted replicable laboratory tests showing that explosion of the lighter was consistent with the failure to extinguish caused by product defect. Engineer's testimony re manufacturing defect is contradicted by widow's other witnesses and by defense experts' lab tests. The chemist admitted that he did not personally examine the lighter and designed a lab experiment to test his hypothesis, but said he "chickened out and shut the experiment down." Experts: Dr. Leighton Sissom, Ph.D. in mechanical engineering (Dean Emeritus of Engineering at Tennessee Technological University in Cookeville, Tennessee); Dr. Lawrence Broutman (research professor in the Department of Mechanical and Materials Engineering at the Illinois Institute of Technology).

- Although BIC's failure-to-extinguish tests were not conclusive in that they did not account for an external heat source causing the lighter body to explode *before* the metal components at the top were ejected, (in the Pride lighter, the spark and flint wheels were found together, a result contrary to that usually observed in traditional failure-to-extinguish cases), the tests did cast doubt on Sissom's conclusions and methodology. *Pride*, 218 F.3d at 573–74.
- After carefully evaluating the testimony of all the experts in light of the standards set forth in *Daubert* and the Federal Rules of Evidence, both the magistrate judge and the district court concluded that the methodologies employed by Pride's expert witnesses were too unreliable to serve as the basis for admissible expert testimony. Pride's experts failed timely to conduct replicable laboratory experiments demonstrating that the explosion and residual damage that occurred in the Pride lighter was consistent with a failure to extinguish incident caused by a manufacturing defect. *Id.* at 578.

Schott v. I-Flow Corp.

696 F. Supp. 2d 898 (S.D. Ohio 2010)

Factual Summary

Several patients brought an action against a pain pump manufacturer, alleging that the pump was defective, causing them to suffer permanent joint damage to their shoulders following orthopedic surgery. The defendant brought motions to exclude general causation testimony from the plaintiffs' experts, arguing that their opinions were not supported by sufficient medical or scientific data, were not generally accepted, and had not been peer-reviewed. The court denied the motions, finding that, testimony from the plaintiffs' general causation experts was reliable and based on a methodology that satisfied *Daubert*.

Key Language

- "The Court sees more than adequate evidence that the expert opinions in this case have been published, subjected to peer review, and are generally accepted by the medical community. The combination of cohort studies, animal studies, and in vitro human cartilage studies demonstrates that the experts' causation opinions are supported by science. The Court respectfully disagrees with the Southern District of Florida's conclusion regarding the Hansen study, which showed 13 out of 19 patients treated with pain pumps developed chondrolysis. The Court has found no authority for the proposition that because 40 percent of patients did not develop chondrolysis, such minority of patients constitutes an 'error rate.' The Court acknowledges difficulty with extrapolation from such a small sample. However, the Court believes that taken together with the body of medical evidence, which is greater than that before the Florida court, the Hansen study only affirms the admissibility of the expert opinions as to general causation." Schott, 696 F. Supp. 2d at 905.
- "The Court further finds Plaintiffs' argument correct that Defendant's attacks on their experts' reports boils down to semantics. The Court finds the Plaintiffs' experts are clearly highly skilled in their respective fields and does not believe they would risk their professional reputations by offering bogus causation opinions before the Court. The Court is satisfied that the body of publications regarding the relation between chondrolysis and anesthetics provides a basis for the general causation testimony offered in this case. Finally, the Court finds Plaintiffs' argument persuasive that they are unable to obtain epidemiological studies, as conducting any

such studies would be unethical. It therefore strikes the Court as unreasonable for Defendant to clamour for such studies." *Id.*

Zink v. SMI Liquidating, Inc. 2010 WL 1839907 (E.D. Ky. May 7, 2010)

Factual Summary

A patient brought an action against a pain pump manufacturer and related entities, alleging that she developed chondrolysis in her shoulder because of a defective catheter that was attached to a pain pump. To support this claim, the plaintiff offered testimony from several experts, including Dr. Samer Hasan, who opined as to the specific causation of the plaintiff's chondrolysis. Hasan claimed to employ a differential diagnosis to reach his opinion. The defendants filed a motion to exclude his testimony, arguing that his attempt at a differential diagnosis was unreliable and improper. The court denied the motion.

- "The Sixth Circuit has explained that differential diagnosis is the 'method by which a physician determines what disease process causes a patient's symptoms. The physician considers all relevant potential causes of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and a thorough case history.' Differential diagnosis is considered to be 'a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Zink*, 2010 WL 1839907, at *3 (quoting *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 178 (6th Cir. 2009)).
- "A review of Dr. Hasan's deposition shows that his proposed testimony as to specific causation satisfies the criteria for admissibility under Rule 702 and *Best*. Dr. Hasan objectively ascertained, by way of the open surgery he performed on plaintiff, that plaintiff has chondrolysis in her shoulder. He further testified that he reviewed her full medical history as it related to her shoulder, including reviewing [a prior physician's] treatment notes. He also testified that he was careful to start from all potential causes of chondrolysis and then 'gradually whittle away and arrive at the most logical explanation." *Id.* at *4.
- "[A]s the court concluded in *Best* about the expert there, the testimony of Dr. Hasan satisfies the criteria for admissibility of differential diagnosis-based opinions. That test does not require the expert to eliminate 'every conceivable' possible cause, and

defendants' criticisms of Dr. Hasan's methodology go to the question of what weight his opinion should be given at trial." Id.

Ky. Farm Bureau Mut. Ins. Co. v. Hitachi Home Elecs. (Am.), Inc. 2009 WL 2589854 (E.D. Ky. Aug 20, 2009)

Factual Summary

In a subrogation action, an insurer alleged that a fire in its insured's home was caused by a television made by the defendant manufacturer. The insurer sought to introduce the testimony of a fire investigator, Eric Evans, to support its allegation that the fire was caused by the television. Evans, applying the methodology for fire investigation outlined in National Fire Protection Association 921: Guide for Fire and Explosion Investigations, concluded that the television was the most likely cause of the fire, but could not identify the specific malfunction. The manufacturer moved to exclude this testimony, arguing that it was not based on reliable investigation techniques. The court denied the defendant's motion, concluding that this methodology was generally accepted and had been reliably applied.

Key Language

- "[E] valuating the reliability of the scientific principles of fire investigation is not needed in this case. These principles, upon which the professional standards outlined in the National Fire Protection Agency [sic] 921 publication ("NFPA 921") are based, have been recognized as the generally accepted standard in the fire investigation community." Hitachi Home Elecs. (Am.), Inc., 2009 WL 2589854, at *2.
- "The theory that must be testable is not Evans' causation theory, but rather the theories underlying the forensic fire investigation standards in NFPA 921, which Evans used to form his causation conclusion.... As previously mentioned, NFPA have been recognized as the generally accepted standard in the fire investigation community. Thus, these scientific theories underlying the fire investigation techniques have already been tested and deemed reliable." Id. at *4.

Galloway v. Big G Express, Inc. 590 F. Supp. 2d 989 (E.D. Tenn. 2008)

Factual Summary

The driver of a tractor trailer, along with the truck's owner and insurer, brought an action against the manufacturer for injuries and damages caused when the windshield collapsed after being struck with water. The plaintiffs sought to introduce the defect opinions of Farhad Booeshaghi, a mechanical engineer. The defendant filed a motion to exclude Dr. Booeshaghi's testimony, arguing that he employed a flawed methodology. The court denied this motion. Specifically, the court held that the general methodology he employed was similar to that used by the defendant's experts, was accepted in the scientific community, and had been reliably applied.

Key Language

- "With regard to scientific knowledge, the trial court must initially determine whether the reasoning or methodology used is scientifically valid and is properly applied to the facts at issue in the trial." Galloway, 590 F. Supp. 2d at 992-93.
- The defendant argues that Dr. Booeshaghi's opinion based on a model that "was simply physically impossible in the real world." Id. at 995. The court responded by stating the "defendant's arguments as to the plausibility of Dr. Booeshaghi's theories is a matter that goes to the weight of the doctor's testimony, which must be left to the jury." Id.
- "[T]he general methodology employed by Dr. Booeshaghi is the same as that employed by the Defendant's experts, use of the scientific method, coupled with engineering principles, to calculate and model the forces allegedly present during the incident. Thus the methodology itself is accepted in the scientific community, though there is no evidence that the specific model established by Dr. Booeshaghi has ever been developed in the past." Id. at 996.

Alfred v. Mentor Corp. 479 F. Supp. 2d 670 (W.D. Ky. 2007)

Factual Summary

The plaintiff allegedly suffered injuries from defective breast implants designed and manufactured by the defendant. The plaintiff sought to introduce testimony from Pierre Blais, Ph.D. to support her claim. The defendant moved to exclude this testimony as unreliable. The court agreed, holding that Dr. Blais used an unreliable methodology and that his opinion was "esoteric, underground, 'aficionado's knowledge"" that relied upon "unsubstantiated and undocumented information" and was "untested and unknown to the scientific community." Alfred, 479 F. Supp. 2d at 673 (quoting Cabrera v. Cordis Corp., 134 F.3d 1418, 1423 (9th Cir. 1998)). Accordingly, the court granted the defendant's motion and excluded his testimony.

Key Language

- "By Dr. Blais'[] own admission, his findings cannot be scientifically tested or evaluated because they do not rest on scientific discoveries and because they are unrelated to scientific theory. Therefore, the court has no basis to assess his theory's reliability beyond Dr. Blais'[] own assurances that it follows inexorably from 'more than a century of research and clinical practice in the control of infectious diseases as well as the work of biomedical pioneers such as Louis Pasteur... and Joseph Lister....' These assurances, however well-founded they may be, are not sufficient safeguards of the reliability and relevance required for the admission of expert testimony under *Daubert* and Rule 702." *Alfred*, 479 F. Supp. 2d at 673 (internal citation to the record omitted).
- "Dr. Blais' opinions are no doubt sincere, but sincerity is not an indication of reliability under *Daubert* or any other reasonable standard for the admission of expert testimony." *Id.* (quoting *Cabrera v. Cordis Corp.*, 945 F. Supp. 209, 214 (D. Nev. 1996)).

Coffey v. Dowley Mfg. 187 F. Supp. 2d 958 (M.D. Tenn. 2002)

Factual Summary

The plaintiff brought a products liability suit against the manufacturer of an automotive tool, alleging that the tool failed while the plaintiff was removing a trapped hub on an automobile. The manufacturer moved to disqualify the plaintiff's expert and for summary judgment. The district court granted both motions. Expert: Dr. Dale Wilson (professor of mechanical engineering at Tennessee Tech. University).

Key Language

• "Methodology employed by professor of mechanical engineering in determining reason for failure of automotive tool while being used by machine being used by mechanic to remove trapped hub from steering knuckle was insufficiently reliable to allow his opinion, where he relied on finite element analysis used primarily to test theoretical models of objects rather than engaging in actual physical testing of exemplar." Coffey, 187 F. Supp. 2d at 958.

Seventh Circuit

Happel v. Walmart Stores, Inc. 602 F.3d 820 (7th Cir. 2010)

Factual Summary

A consumer who was diagnosed with Multiple Sclerosis ("MS") brought suit, along with her husband, against a pharmacy, alleging that it negligently filled a prescription for medication that included an ingredient to which she was allergic. The plaintiff claimed that her reaction to this medication precipitated a rapid decline in her health by exacerbating her MS symptoms. To support this claim, she offered the testimony of Dr. Alan Hirsch, a neurologist, who opined that the stress from the drug allergy caused an exacerbation of her MS. He offered no experimental, statistical, or scientific data to support his opinion. The district court excluded Dr. Hirsch, in part, because his methodology for reaching his conclusion was insufficient and unreliable. The Seventh Circuit concluded that the district court did not abuse its discretion in excluding his opinions.

Key Language

• "Some physicians rely on treatises, medical tests, and laboratory findings to reach their causation conclusions, while others conduct a differential diagnosis to rule out the least plausible causes of illness. However, Dr. Hirsch does not cite any of these methodologies in his attempt to demonstrate the causal relationship between stress and MS; rather, he relies solely on his past experience and the temporal proximity of [the plaintiff's] allergic reaction and recurring MS symptoms. This does not an expert opinion make. To the extent that Dr. Hirsch does rely on medical literature to support his theory, the articles to which he cites stop short of reaching the same conclusion. Indeed, one of the articles directly contradicts his theory... At best, Dr. Hirsch's testimony would have amounted to an 'inspired hunch,' and the district court certainly did not abuse its discretion in excluding it." Id. at 825-26 (quoting Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996)) (internal citation and footnote omitted).

Am. Honda Motor Co., Inc. v. Allen 600 F.3d 813 (7th Cir. 2010)

Factual Summary

Purchasers of a specific model of motorcycle brought a purported class action against the manufacturer, alleging that the motorcycle had a design defect that prevented it from sufficiently dampening the bike's "wobble." To establish the predominance element of their class action, they offered the testimony of Mark Ezra, a purported motorcycle engineering expert. Ezra opined that the bike failed to meet a wobble standard

that he had created and previously published. To reach this conclusion, Ezra conducted testing on one used bike of the model at issue that had been restored to factory condition. The manufacturer moved to strike this report as inadmissible pursuant to *Daubert*, arguing that Ezra's standard was unreliable and, even if it was, he did not reliably apply it because his testing was deficient. The district court declined to strike Ezra's report prior to class certification, determining that it was sufficiently reliable. On an appeal of the district court's decision to grant class certification, the manufacturer argued that the district court erred by failing to strike Ezra's testimony. The Seventh Circuit agreed, concluding that Ezra's standard was speculative and that his methodology was unreliable. As a result, it concluded that the district court erred by failing to strike it.

Key Language

• "The methodology underlying the tests Ezra conducted to determine whether the [subject motorcycle model met his standard also gives us pause. Ezra tested a single, used 2006 GL1800, ridden by a single test rider, and extrapolated his conclusions to the fleet of GL1800s produced from 2001 to 2008. 'Determining the minimum sample size from which reliable extrapolations can be made to the sampled population is tricky,' but a sample size of one is rarely, if ever, sufficient.... The small sample size also highlights the constraints litigation placed upon Ezra's methods and professional judgment; Ezra was not being as thorough as he might otherwise be due to Plaintiffs' reluctance to pay for more testing." Allen, 600 F.3d at 818 (quoting DeKoven v. Plaza Assocs., 599 F.3d 578, 581 (7th Cir. 2010)) (internal citations omitted).

Winters v. Fru-Con Inc. 498 F.3d 734 (7th Cir. 2007)

Factual Summary

A worker at a food processing plant brought a products liability claim against the company that installed factory equipment that injured him. To support this claim, the plaintiff offered the testimony of Edmond Israelski, a purported human factors expert, and H. Boulter Kelsey, a mechanical engineer, who testified that various components of the equipment that injured the plaintiff were defectively designed. The trial court, a magistrate judge, barred this testimony, concluding that their methodology was speculative and both experts had not tested their alternative designs, rendering their opinions unreliable. On appeal, the Seventh Circuit held that Israelski and Kelsey's failure to test alternative designs, or to take any action to compensate for the lack of testing, rendered their methodology unreliable. Accordingly, it affirmed.

- "'In alternative design cases, we have consistently recognized the importance of testing the alternative design' as a factor that the district court should consider in evaluating the reliability of the proposed expert testimony. Testing an alternative design can assist a proposed expert in considering: (1) the alternative's compatibility with existing systems, (2) relative efficiency of the current versus alternative design, (3) short and long term maintenance costs for the alternative design, (4) ability of the proposed purchaser to service and maintain the alternative design, (5 cost of installing the alternative design, and (6) change in cost to the machine. 'Many of these considerations are product and manufacturer specific and cannot be reliably determined without testing' of the alternative design." Winters, 498 F.3d at 742 (quoting Dhillon v. Crown Controls Corp., 269 F.3d 865, 870 (7th Cir. 2001)) (internal citations omitted).
- "Although testing an alternative design will likely be advantageous in demonstrating that the proposed expert's testimony is reliable, we have not mandated alternative design testing as 'an absolute prerequisite to the admission of expert testimony' because the Daubert inquiry is a 'flexible inquiry.' There could be situations where the district court determines the proposed expert's testimony regarding an alternative design is reliable despite a lack of testing of the alternative design because the expert has adhered to the 'standards of intellectual rigor that are demanded in [his or her] professional work,' such as relying on the data generated by other researchers, making proper personal observations or taking other appropriate actions." Id. at 742-43 (quoting Cummins v. Lyle Indus., 93 F.3d 362, 368-69 (7th Cir. 1996)) (alterations in original).
- "The district court properly exercised its discretion in finding that Winters' proposed experts were not reliable and therefore properly rejected their tendered expert testimony. The proposed experts both failed to test their alternative designs and also failed to utilize any other method of research to compensate for their lack of alternative testing. Thus, their proposed opinion is based on a belief that alteration to add a safety improvement is appropriate and therefore there is no need to determine the reliability of their alternatives. 'Simply put, an expert does

not assist the trier of fact in determining whether a product failed if he starts his analysis based upon the assumption that the product failed (the very question that he was called upon to resolve)." *Id.* at 743 (quoting *Clark v. Takata Corp.*, 192 F.3d 750, 757 (7th Cir. 1999)).

Ervin v. Johnson & Johnson, Inc. 492 F.3d 901 (7th Cir. 2007)

Factual Summary

A patient brought a products liability action against various drug manufacturers, alleging that a prescription medication for treating his Crohn's disease caused a blood clot, specifically, an arterial thrombosis, which required his leg to be partially amputated. To support this claim, he offered the testimony of Dr. Lee McKinley, a purported medical causation expert. Dr. McKinley opined that the plaintiff's use of the drug caused his arterial thrombosis after relying on a differential diagnosis. In order to "rule in" the prescription drug as a possible cause, he relied on the temporal proximity of the clot to when the plaintiff began taking the drug, an internet search that provided a single case report, and basic line entries from Food and Drug Administration printouts. He did not consider the plaintiff's other medical conditions. The district court granted the defendant's motion in limine to exclude McKinley's testimony, concluding that it was unreliable. The Seventh Circuit affirmed.

Key Language

- "A differential diagnosis satisfies a *Daubert* analysis if the expert uses reliable methods. Under *Daubert*, expert opinions employing differential diagnosis must be based on scientifically valid decisions as to which potential causes should be 'ruled in' and 'ruled out.' Determining the reliability of an expert's differential diagnosis is a case-by-case determination." *Ervin*, 492 F.3d at 904 (quoting *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005)).
- "We agree with the district court that Dr. McKinley had no reliable basis for his expert opinion. He could not point to any epidemiological data supporting his opinion, and he was not able to articulate any scientifically physiological explanation as to how [the drug at issue] would cause arterial thrombosis. The mere existence of a temporal relationship between taking a medication and the onset of symptoms does not show a sufficient causal relationship." *Id.* at 904–05.

Chapman v. Maytag Corp. 297 F.3d 682 (7th Cir. 2002)

Factual Summary

The plaintiff's husband was electrocuted when he touched a heating duct that had become an energized surface. The plaintiff had installed a Maytag range. The range's power cord was damaged during shipment, coming underneath a sharp corner of the range. Compounding the problem, the decedent had used an ungrounded outlet for a grounded plug and did nothing to properly ground the unit. The plaintiff alleged that damage to the power cord (worn insulation) caused the introduction of current into the stove, its surrounding area, and then eventually the heating duct. While the defendant agreed that the cord introduced the current into the house and its components, the defendant contended that the fatal shock would not have occurred if the decedent had properly grounded the unit. The defendant averred, through an expert, that a properly grounded unit would have caused the circuit breaker to trip and thereby prevented the accident. The plaintiff's expert stated that because the current built up slowly in the house it was enough to electrocute, but not enough to trip the breaker, as it was a "resistive short." The plaintiff's expert could only represent to the court that he was "currently designing a testing procedure which when completed will conclusively prove this theory to be true." However, at the time of the testimony his theory was untested. The defendant, citing Daubert, moved unsuccessfully to exclude the plaintiff's expert. The Seventh Circuit reversed, stating that district court's admission of plaintiff's expert was error. Expert: James Petry (mechanical engineer, on electrical breaker panel function).

Key Language

- "A very significant *Daubert* factor is whether the proffered scientific theory has been subjected to the scientific method.... Personal observation is not a substitute for scientific methodology and is insufficient to satisfy *Daubert*'s most significant guidepost." *Chapman*, 297 F.3d at 688.
- Testimony was improperly admitted where no proof offered that theory is generally accepted in the scientific community. *Id*.

Dura Auto. Sys. of Ind., Inc. v. CTS Corp. 285 F.3d 609 (7th Cir. 2002)

Factual Summary

The plaintiff alleged that the defendant's industrial process had contributed to contamination of ground-

water and sought recovery of clean-up costs. To succeed, the plaintiff needed to show that the defendant was within a geographical area that would have been expected to lead to contamination. The district court excluded the plaintiff's expert from testifying about pollution to groundwater because. in arriving at the opinion that the defendant's plant had contributed to the pollution, the expert had relied on the opinion of experts outside his own area of expertise. The Seventh Circuit affirmed. Expert: Nicholas Valkenburg (hydrogeologist, on groundwater flow).

Key Language

• "A scientist, however well credentialed he or she may be, is not permitted to be the mouthpiece of a scientist in a different specialty." *CTS Corp.*, 285 F.3d at 614.

Dhillon v. Crown Controls Corp. 269 F.3d 865 (7th Cir. 2001)

Factual Summary

While operating a forklift made by the defendant, the plaintiff was injured when his leg fell out of the driving compartment and was pinned against a beam. The plaintiff contended that the design of forklift without a back door caused his injury. The district court prevented the plaintiff's proffered experts from testifying that a back door would have prevented injury by safeguarding the plaintiff's leg from falling out of the compartment. The Seventh Circuit affirmed, concluding that the proffered testimony did not meet the *Daubert* methodology because neither expert performed any testing of alternative designs nor did either expert have any prior experience in the design of forklifts. Experts: John B. Sevart (mechanical engineer); Dr. Gerald Harris (biomechanical engineer) on alternative design.

Key Language

- "[T]he most glaring [problem with proffered testimony] is the lack of testing, or more generally the failure to take any steps that would show professional rigor in the assessment of the alternative designs (or, as the amended rule puts it, that the testimony is 'the product of reliable principles and methods')." *Dhillon*, 269 F.3d at 869.
- "In alternative design cases, we have consistently recognized the importance of testing the alternative design." *Id.* at 870.

Bourelle v. Crown Equip. Corp. 220 F.3d 532 (7th Cir. 2000)

Factual Summary

The plaintiffs sued a forklift manufacturer for injuries sustained when empty pallets fell off the fork and, after bouncing on the ground, entered the driver's compartment causing injury to the driver's abdomen and knee. The court excluded the plaintiffs' expert from testifying that an alternative design, raising the height and coverage of the already existing safety bars, would have prevented the injury. The expert failed to comport with the Daubert methodology because he performed no tests and thus had no scientific basis for his opinion relative to alternative design. His opinion did not pass muster for unsafe warnings for a similar reason. All the expert did to prepare his opinion was read depositions, and manuals for the forklift. The Seventh Circuit affirmed. Expert: Daniel Pacheco (mechanical engineer, alternative design).

Key Language

• The trial judge focused on the lack of testing performed by the plaintiff's expert. As to an opinion on warnings for the forklift, judge properly excluded his opinion as "the fact that [the expert] never even drafted a proposed warning renders his opinion akin to 'talking off the cuff." *Bourelle*, 220 F.3d at 539.

Braun v. Lorillard, Inc. 84 F.3d 230 (7th Cir. 1996)

Factual Summary

The plaintiff died of mesothelioma, a type of lung cancer most commonly associated with corcidolite asbestos. The defendant sold Kent cigarettes that had filters containing this type of asbestos. Central to the plaintiff's case was the issue if examination of the defendant's lung tissue had revealed the presence of asbestos fibers. All of the plaintiff's experts, except Dr. Schwartz, had failed to find the fibers using the usual methods of detection. Dr. Schwartz, who examined ceiling tiles for the presence of asbestos, used the method for that application on the lung tissue. He tested the tissue under high heat (high temperature ashing) with the premise that the asbestos would burn off last because of its resistance to high temperatures. Dr. Schwartz had a lab technician perform the experiment. The technician orally reported the result that the test detected a presence of the fibers. The Seventh Circuit held that the trial court properly rejected Dr. Schwartz's opinion because of the improper methodology of the experiment. Expert: Dr. David Schwartz (biochemist, on asbestos detection).

Key Language

- "Although Schwartz is an acknowledged expert on the testing of building materials for asbestos, he had never before conducted a test on human or animal tissue. Nor, so far as it appears, has high temperature ashing ever been used by anyone else to test for the presence of asbestos fibers in tissue." *Braun*, 84 F.3d at 233.
- "Nowhere in *Daubert* did the court suggest that failure to adhere to the customary methods for conducting a particular kind of scientific inquiry is *irrelevant* to the admissibility of a scientists' testimony. On the contrary the court made clear that it is relevant.... If, therefore, an expert proposes to depart from the generally accepted scientific uncertainty, the court may appropriately insist that he ground his departure in demonstrable and scrupulous adherence to the scientist's creed of meticulous and objective inquiry." *Id.* at 235.
- "Daubert and its sequelae are aimed [at the]... abuse [of] the hiring of reputable scientists, impressively credentialed, to testify for a fee to propositions that they have not arrived at through the methods that they use when they are doing their regular professional work rather than being paid to give an opinion helpful to one side in a lawsuit." *Id*.

Meyers v. Nat'l R.R. Passenger Corp. 648 F. Supp. 2d 1032 (N.D. Ill. 2009)

Factual Summary

A pipe fitter and sheet metal worker for Amtrak brought an action under the Federal Employers' Liability Act, alleging that Amtrak failed to provide an adequate ergonomic program, which resulted in his exposure to harmful cumulative trauma in his work environment. To support this claim, the plaintiff offered the testimony of Dr. Gail Rousseau to establish causation between him work responsibilities and his injuries. Dr. Rousseau's "report" stated that she reviewed the plaintiff's medical records and job description and, as a result, believed that his injuries were aggravated by his work, which the plaintiff argued constituted a differential diagnosis. Amtrak moved to strike the report, affidavit, and opinions of Dr. Rousseau, along with those of the plaintiff's other two experts, arguing that this methodology was insufficient to satisfy *Daubert* or Rule 702. The court granted this motion.

Key Language

- "Amtrak notes that absent from Rosseau's report is any indication of what methods were used by Rosseau to reach her conclusion.... It is true that '[a] differential diagnosis satisfies a Daubert analysis if the expert uses reliable methods.' However, merely citing to differential diagnosis in general is not enough to automatically show that a reliable methodology was used. In this case, it is impossible to even assess whether Rosseau's differential diagnosis was properly conducted since Rosseau, herself, does not even affirmatively state that she used a differential diagnosis. Ultimately, there is no information offered by Meyers to show the soundness of Rosseau's methodology underlying her conclusion." Meyers, 648 F. Supp. 2d at 1045 (quoting Ervin v. Johnson & Johnson, 492 F.3d 901, 904 (7th Cir. 2007)) (internal citations omitted).
- "[C]iting differential diagnosis is not a catch-all that automatically provides a valid basis for the reliability of expert opinions. Even when differential diagnosis is used by a medical expert, it is necessary to show that such a method was properly executed." *Id.* at 1046.

Schmude v. Tricam Indus., Inc. 550 F. Supp. 2d 846 (E.D. Wis. 2008)

Factual Summary

A hospital worker brought a products liability action against a ladder manufacturer when the ladder he was using to install equipment in the hospital collapsed, causing him to fall and sustain injuries. The manufacturer did not dispute that the ladder had a manufacturing defect, but argued that the accident was caused by the plaintiff's failure to use due care for his safety. After the jury returned a verdict in the plaintiff's favor, the defendant moved for a new trial, arguing, in part, that the court erred by permitting the testimony and in-court demonstration of the plaintiff's design expert Stanley Johnson. Johnson did not test his opinion as to how the ladder failed. Rather, during trial, he demonstrated how, by jerking the ladder towards him, the ladder's leg dislodged and rendered it unstable. The court concluded that Johnson's opinion and demonstration, given the relatively simple nature of the case, were based on appropriate methodologies and had been properly admitted.

Key Language

• "In sum, there is no singular well-accepted, standardized way for an engineer with manufacturing experience to reconstruct an accident involving a ladder with a specific and unique defect that could not be duplicated, and I am satisfied that Johnson's method was as sound as can be expected; in fact it is difficult to imagine how else the plaintiff could have gone about demonstrating his theory to the jury." Schmude, 550 F. Supp. 2d at 853.

• "Scientific precision is not possible in a case of this nature, and when the case involves recreating a relatively simple accident, the court's gatekeeping role is limited by the simple fact that a jury is more than capable of distinguishing between plausible and implausible explanations and weighing the expert's presentation against the other evidence. In other words, in my view, this was a case in which the adversarial process was fully able to explain alternatives to the jury without the possibility that the jury would be swayed by unscientific principles or improper testimony. The theory that a stepladder may collapse if the rivet fastening one of the legs to the cap fails is not 'rocket science." Id.

McCloud ex rel. Hall v. Goodyear Dunlop Tires N. Am., Ltd. 479 F. Supp. 2d 882 (C.D. Ill. 2007)

Factual Summary

After the tire on their motorcycle blew out while they were riding, the driver and passenger brought an action against the tire manufacturer, alleging that the resulting crash was caused by a manufacturing defect in the tire. To support their claim, the plaintiffs offered testimony from Gary Derian and William Woerhle, mechanical engineers. Both Derian and Woerhle reached their initial defect opinions after a three-hour visual and tactile inspection. Woerhle also conducted tests on a single tire by running it for a specific number of miles. The manufacturer moved to bar both Derian and Woerhle's testimony, arguing, inter alia, that it was based on a flawed and unreliable methodology. The court concluded that both experts' use of a nondestructive visual and tactile examination of the failed tire was an accepted methodology, and that Woerhle's testing, although imprecise, was sufficiently reliable. As a result, the court denied the defendant's motion to bar their testimony.

Key Language

- "The law suggests that nondestructive visual and tactile examination of a failed tire is accepted in the field of tire forensics." McCloud, 479 F. Supp. 2d at 890.
- · "Defendant also argues that Woerhle and Derian conducted their inspections and reached their expert

opinions 'too quickly.' Specifically, Woerhle and Derian both reached their initial conclusion that the tire was defective in less than three hours. This position is an example of an argument that goes to the weight rather than the admissibility of an expert's testimony. From a defendant's perspective, experts, hired by a plaintiff, reach a conclusion which is sought by the plaintiff. The fact that they reached that conclusion quickly makes it seem more likely that their testimony was geared toward the plaintiff's wishes—in short, it goes to credibility. However, from a plaintiff's perspective, experts can reach their conclusion quickly because they have considerable experience and because the evidence is so clear that that no additional time is needed." Id. at 891.

- "Without additional facts, when an expert reaches their conclusion quickly, it only goes to the expert's credibility with the proper spin and alone does not undermine the expert's reliability. After all, we expect the jury to evaluate conflicting experts over a limited period of time. Even without any prior experience or knowledge on the subject, if they reach a conclusion in a few hours, their findings are still given the full faith and credit of the law. Accordingly, visual and tactile inspections, even if performed quickly, still meet the professional standard for tire investigations in this case." Id.
- "To meet the testing factor required by *Daubert*, an expert does not need to perform the best conceivable test. Instead, the question is whether valid scientific testing was performed." Id. at 892.

Auto-Owners Ins. Co. v. Uniden Am. Corp. 503 F. Supp. 2d 1087 (E.D. Wis. 2007)

Factual Summary

The insurer of a condominium that was damaged in a fire brought a subrogation action against a phone manufacturer, alleging that a defective phone caused the fire. The insurer offered the testimony of Paul Hansen, a purported fire cause and origin expert. Hansen conducted a joint examination of the premises and a destructive examination of the phone at issue. In his report, he claimed that he ruled out other potential sources of the fire through physical examination of other sources in the proximity of the fire, leaving the phone as the only possible cause. He then conducted testing of the phone to determine if it contained combustible materials. The manufacturer attacked the methodology underlying Hansen's opinions and moved to strike his testimony. The court concluded that his methodology was appropriate for his opinion that the

phone was the cause of the fire, but unreliable for his additional opinion that a defect in the phone caused the fire, as he did not identify any specific defect, failure mechanism or eliminate other potential causes for the phone's malfunction. As a result, the court granted-in-part and denied-in-part the manufacturer's motion to strike Hansen's testimony.

Key Language

- "As an initial matter, process of elimination is an acceptable methodology in the scientific and engineering communities. An opinion regarding causation based on the detailed elimination of other potential causes is thus based on a reliable methodology." *Auto-Owners Ins. Co.*, 503 F. Supp. 2d at 1093 (internal citations omitted).
- "In sum, I conclude that Hansen's opinion that the phone caused the fire is based on methodology that is sufficiently reliable. Hansen identified the phone as the source of the fire based on a detailed application of the process of elimination, as well as evidence affirmatively supporting his opinion that the phone was the cause. Hansen then confirmed that the phone could be the ignition source based on his own tests and the well accepted scientific literature discussing components of the phone in question." *Id.* at 1095.
- "The methodology used by Hansen to determine the source and cause of the fire does not also provide support for his conclusion regarding whether there existed a defect at the time of manufacture. As such, Hansen has not provided a scientific basis for his conclusion that the phone's failure was due to a manufacturing or design defect, and this conclusion is inadmissible speculation. To begin with, Hansen has not identified any potential manufacturing or design defects which could have resulted in the phone's failure. Hansen is unable identify any particular defect because of the damage to the phone, and has thus not provided evidence of any specific defects within the phone which could have triggered the fire. Although Hansen has identified potential failure mechanisms, he has not specifically linked these mechanisms to a manufacturing or design defect in the phone. Furthermore, Hansen did not eliminate other potential causes for the phone's malfunction outside of an internal defect.... Moreover, Hansen has not eliminated any other sources which could have caused the phone's 'defect' during the five years since the purchase of the phone. Without any basis for his opinion that the phone was defec-

tive and unchanged since its manufacture, Hansen's opinion is pure speculation." *Id.* at 1096.

Baker v. Buffenbarger 2006 WL 140548 (N.D. Ill. Jan. 13, 2006)

Factual Summary

The plaintiffs, union members, brought suit against their union for free-speech violations. The plaintiffs sought to exclude the testimony of the defense expert on the grounds that he used no reliable methodology in forming his opinion. The court concluded that the expert's experience and knowledge was sufficient. Expert: Dr. Ray Marshall (labor/coordinated bargaining).

Key Language

- "With regard to 'methodology,' it is true that Dr. Marshall did not apply any sort of standardized or generally accepted test or method in arriving at the conclusions he reached. Indeed, at his deposition, he testified that, in opining that both the trusteeship of Local 701 and the suspensions of Elam and Baker were appropriate, he relied on 'some general principles' and on 'judgment,' but did not rely on any kind of methodology or testing procedure. But it is unquestionably true that Dr. Marshall has a wide body of experience in the labor field and in union dealings from which to draw. And experience alone may be enough." *Baker*, 2006 WL 140548, at *5.
- "Based on his considerable experience, the Court is persuaded that Dr. Marshall may reliably testify on the subjects of coordinated bargaining and on the general labor principles at issue in this case. Although the plaintiffs emphasize that Dr. Marshall has never participated in a coordinated bargaining process and has never testified as an expert on this particular issue—both of which may be true, Dr. Marshall unquestionably has vast experience in the labor field and in union/employer negotiations and dealings." *Id.* at *6.

State Farm Fire & Cas. Co. v. Toshiba Am. Consumer Prods., Inc. 2006 WL 897781 (E.D. Wis. Mar. 31, 2006)

Factual Summary

The plaintiff insurance company filed a subrogation suit to hold the maker of an allegedly defective television set liable for the fire that destroyed a home. The defendants sought to exclude the testimony of the plaintiff's expert as being scientifically unreliable, but failed to state specifically how the expert failed to

employ the scientific method. The court held that the expert did follow industry standards and that his testimony was reliable. Expert: Paul Hansen (forensic electrical engineering).

Key Language

- "Toshiba claims that Hansen's methodology was irreparably flawed because he failed to rule out other causes of the fire and did not employ deductive reasoning. Toshiba has not cited any case law stating that a failure to rule out causes of a defect or condition render an expert's opinion per se inadmissible." State Farm Fire & Cas. Co., 2006 WL 897781, at *8.
- "In this circuit, however, elimination of other causes when determining probable cause is not a prerequisite to establish reliable methodology." Id.

Dewick v. Maytag Corp. 324 F. Supp. 2d 894 (N.D. Ill. 2004)

Factual Summary

The parents of ten-month old child brought a products liability action arising from an incident where the child climbed into the broiler compartment of a kitchen range made by Maytag Corporation. Maytag moved to have the plaintiff's expert testimony excluded on the grounds that the methods employed were not specifically germane to this accident. The court held that the methodology employed was reliable and relevant regarding the safety of the original range, but testimony as to alternative designs would be excluded. Expert: Jack E. Hyde (product safety).

Key Language

- "Maytag's contention (M.Mem.1:16, M.R. Mem.1:1-3) that, because Hyde has never previously analyzed the specific safety issue of how a 10-month old infant interacts with a broiler door, he is somehow unqualified to render an opinion here takes far too restrictive a view of what Rule 702 calls for as to the scope of a witness' expertise." Dewick, 324 F. Supp. 2d at 898.
- "To the contrary, this Court holds that the methodologies Hyde did employ (including performing force tests, making calculations using anthropometric data and reviewing other publicly available information about existing ranges with features similar to his suggested changes) sufficiently guarantee that certain of his opinions—those as to the safety (or lack of safety) of the original range and as to the alternative designs of a recessed handle and a modified pivot door—are not meaningless conclusions drawn with no substantiating analysis." Id. at 899.

Holden Metal & Aluminum Works v. Wismarg Corp. 2003 U.S. Dist. LEXIS 5247 (N.D. Ill. Apr. 2, 2003)

Factual Summary

The plaintiff manufacturer filed suit against the defendant contractors, alleging breaches of warranty and contract. The district court granted the contractor's motion to bar testimony of the plaintiff's expert.

Key Language

• "In summary, Brown's failure to conduct actual tests, to employ any identifiable methodology, and to sufficiently take into account existing data and research are not surprisingly revealed by his inability to state to a reasonable degree of scientific certainty which of his five possible failure theories alone or in combination are the reason for the alleged failure.... Brown's testimony is so unreliable that it fails to pass muster under Daubert and Kumho." Wismarq Corp., 2003 U.S. Dist. LEXIS, at *9.

Frey v. Chicago Conservation Ctr. 419 F. Supp. 2d 794 (N.D. Ill. 2000)

Factual Summary

The plaintiff offered an expert who would testify that the plaintiff's art had been treated with ozone while stored by the defendant as a way to clean the art after it had been exposed to smoke. The expert's basis was his observation of altered colors and his smelling ozone on the art. The court concluded that the expert's smell and visual method of inspection was not sufficiently sound and must be excluded. Expert: Patrick B. King (art conservationist, on property damage).

Key Language

- Daubert test is flexible and sufficient demonstration of one prong may be sufficient to meet burden. Frey, 419 F. Supp. 2d at 797–98.
- "The [expert's] methodology (I smelled it, I saw it therefore it is) is simply too subjective, unsupported and speculative to be considered reliable for purposes of FRE 702 at 798." Id. at 798.

Collier v. Bradley Univ.

113 F. Supp. 2d 1235 (C.D. Ill. 2000)

Factual Summary

The plaintiff sued, claiming racial discrimination in employment after the defendant denied her tenure. The plaintiff offered an expert in social psychology to support her claims of discrimination and damages. The court excluded the expert because she failed to articulate any scientific (or other) methodology employed to reach her opinion. Expert: Dr. Midge Wilson (social psychologist, on discrimination and its effects).

Key Language

• Expert barred "if [the expert] is unable to specify what type of methodology she employed in this case, it is impossible for this Court to evaluate the propriety of that methodology." *Collier*, 113 F. Supp. 2d at 1244–45.

United States v. Fujii 152 F. Supp. 2d 939 (N.D. Ill. 2000)

Factual Summary

The government attempted to use a handwriting expert to prove that the defendant, a Japanese national, had printed information onto an immigration form for the attempted illegal entry of two Chinese nationals. The court excluded the expert from giving an opinion as to whether the defendant hand-printed certain immigration forms. The court questioned the scientific methodology of handwriting analysis as a discipline, but held explicitly that where English handwriting was done by a native Japanese, *i.e.*, foreign trained writer, handwriting expert not supported her analysis by sufficient methodology. The fact that the defendant was not a native writer of English undermined the assumptions of her methodology. Expert: Karen Ann Cox (handwriting analyst, on handwriting identification).

Key Language

• "Handwriting analysis does not stand up well under the *Daubert* standards... [as] validation studies supporting its reliability are few, and the few that exist have been criticized for methodological flaws." *Fujii*, 152 F. Supp. 2d at 940.

*Valente v. Sofamor, S.N.C.*48 F. Supp. 2d 862 (E.D. Wis. 1999)

Factual Summary

The plaintiffs elected to have a back surgery to relieve pain caused by an earlier injury. The surgery consisted of fusing together two vertebrae through the use of pedicle or bone screws. After the surgery, the plaintiffs complained of increased pain. The court barred the plaintiffs' expert because he did not demonstrate that he followed a scientific method in reaching his opinions, rendering them conclusory. The expert concluded that because the plaintiffs' pain went away after having bone screws removed, the screws were the source of the pain. The court held that this was legally insuf-

ficient because the expert neither considered nor ruled out any other possibilities for the injury, including the fusion surgery that the plaintiffs had elected despite the risk of further injury. Expert: Dr. Steven Trobiani (neurologist, on causation).

Key Language

• "[The expert] simply assumes that if A occurred before B, then A must have caused B. Such reasoning cannot qualify as expert testimony." *Valente*, 48 F. Supp. 2d at 872.

Navarro v. Fuji Heavy Indus., Ltd. 925 F. Supp. 1323 (N.D. Ill. 1996)

Factual Summary

The plaintiff sued over an alleged defect in a car's suspension system. Eleven years after manufacture, through multiple owners and without regular professional maintenance, the suspension corroded and broke, thereby allegedly causing the car to slide off the road and flip over. One expert opinion was barred as not relevant nor based on "scientific knowledge." The other expert was excluded for rendering merely conclusory opinion. Expert: Maurice Howes (metallurgical consultant, on corrosion and causation).

Key Language

- "Experts cannot float their conclusions on cushions of air, they must rest those conclusions upon foundations built from reliable scientific explanation." *Navarro*, 925 F. Supp. at 1328.
- "An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process...
 [w]hy should a court rely on the sort of exposition...
 [a]... scholar would not tolerate in his professional life?" *Id.* at 1329 (citations omitted).

Eighth Circuit

Barrett v. Rhodia, Inc. 606 F.3d 975 (8th Cir. 2010)

Factual Summary

A technician at a hazardous waste disposal plant, along with his employer, brought a toxic tort action against a chemical manufacturer, alleging that defects in the drum storing the company's chemical resulted in the creation of toxic gas that caused the technician injury, as well as that the drum failed to warn of the potential exposure. To support these claims, the plaintiffs retained several experts, including Edward Ziegler, a safety engineer. After visiting the facility and observ-

ing how the drums of chemicals were housed, Ziegler opined that defects existed in the drums supplied by the manufacturer, resulting in the formation of toxic gas, and that the gas caused the technician's injuries. The defendant filed a motion in limine challenging Ziegler's testimony, as well as the plaintiffs' other experts. The district court granted this motion in part, but permitted Ziegler to testify as to the facility's monitoring and safety practices. The court granted the defendant's subsequent motion for summary judgment. On appeal, the plaintiffs argued, in part, that the district court erred by limiting and/or excluding their experts' testimony. The Eighth Circuit affirmed.

Key Language

- "Expert testimony is inadmissible where, as here, it is excessively speculative or unsupported by sufficient facts." Barrett, 606 F.3d at 981.
- "Ziegler conceded that he relied entirely on the opinions of appellants' physician experts for his proposed testimony on the dispersal of hydrogen sulfide gas, the concentration of Barrett's exposure to the gas, and the source of that exposure. He did not conduct any chemical analysis, measuring, or dispersion modeling.... Under *Daubert*, an expert's opinion must be 'derived by the scientific method' or otherwise 'supported by appropriate validation.' The district court did not abuse its discretion by concluding that Ziegler's opinion lacked scientific or other appropriate validation." Id. at 983 (quoting Daubert, 509 U.S. at 590).
- "Given that part of Ziegler's proposed testimony was based primarily on assumptions instead of testing, measurement, or scientific analysis, the district court did not abuse its discretion in limiting it." *Id*.

Presley v. Lakewood Eng'g & Mfg. Co. 553 F.3d 638 (8th Cir. 2009)

Factual Summary

A homeowner brought an action against a manufacturer, alleging that its space heater resulted in a fire that caused personal injury and property damage. To establish causation, the homeowner offered the testimony of Raymond D. Arms, a fire investigator and electrical engineer. Arms investigated the cause of the fire and, in addition to his observations and analysis of testing, relied on NFPA 921: Guide for Fire and Explosive Investigations, other literature, the scientific method, and his experience. The manufacturer moved to exclude Arms' testimony, arguing that he did not reliably apply NFPA 921 and failed to adequately test or provide scientific evidence to support his causation theory. After a Daubert hearing, the district court agreed and excluded Arms' testimony. On appeal, the plaintiff asserted the district court applied an overly rigid standard of reliability when evaluating Arms' methodology. The Eighth Circuit disagreed. Specifically, it found that Arms' methodology did not comply with NFPA 921, was unsubstantiated by any scientific testing, and was therefore unreliable. Accordingly, the Eighth Circuit affirmed the district court's exclusion of his testimony.

Key Language

- "While weighing these factors, the district court must continue to function as a gatekeeper who 'separates expert opinion evidence based on good grounds from subjective speculation that masquerades as scientific knowledge." Presley, 553 F.3d at 643 (quoting Glastetter v. Novartis Pharms. Corp., 252 F.3d 986, 989 (8th Cir. 2001)).
- "In certain circumstances, a fire expert can offer a reliable opinion based upon specific observation and expertise." Id. at 644.
- "NFPA 921 requires appropriate data analysis and testing. Further, NFPA 921 suggests that fire theories involving an appliance be substantiated by testing of exemplar appliances. Arms failed to follow these aspects of the standards he purported to follow." Id. at 645 (internal citations omitted).
- "Our court has previously held opinions formulated merely upon general observations of the evidence and general scientific principles were unreliable." Id. at 646.
- "Testing, which is actually performed, must be appropriate and must analytically prove the expert's hypothesis." *Id*.
- "An expert generally cannot formulate a theory through supposition based on his or her own expertise." Id. at 647.

Shuck v. CNH Am., LLC. 498 F.3d 868 (8th Cir. 2007)

Factual Summary

The owners of a combine brought a products liability action against the manufacturer after a fire occurred in the combine's engine compartment. The plaintiffs offered testimony from Ken Ward, a fire cause and origin expert, and Steven Mikesell, a mechanical expert, to support their claims. Both experts relied upon post-fire inspections of the combine and its components. Neither conducted any testing to support their opinions. After the jury returned a verdict for the plaintiffs, the manufacturer appealed, asserting that the district court erred by failing to exclude Ward and Mikesell's testimony because both employed flawed and unreliable methodology. The Eighth Circuit disagreed and affirmed.

Key Language

- "When a litigant clearly believes a certain methodology is acceptable as shown by his or her own expert's reliance on that methodology, it is disingenuous to challenge an opponent's use of that methodology." *Shuck*, 498 F.3d at 874.
- "The failure to test components that were damaged or destroyed by fire did not necessarily render the experts' methodology flawed nor opinions inadmissible. Here, Ward and Mikesell testified that certain components could not be tested due to the destruction or alteration of the components in the fire or due to the arrangement of the components in the damaged engine.... In such a situation, observations coupled with expertise generally may form the basis of an admissible expert opinion." *Id.* at 874–75.
- The court noted that precedent "[did] not stand for a bright line rule that expert opinions in fire cases always must be supported by testing to be admissible. Rather, [it] stands for the more general propositions that testing, if performed, must be appropriate in the circumstances and must actually prove what the experts claim it proves." *Id.* at 875 n.3.

Olson v. Ford Motor Co. 481 F.3d 619 (8th Cir. 2007)

Factual Summary

The estate of an intoxicated driver who crashed his vehicle while attempting to navigate a curve filed suit against the manufacturer, alleging that the vehicle contained a defectively designed cruise control actuator cable that caused the vehicle to accelerate unexpectedly. In addition to countering the plaintiff's defect theory, the defendant offered testimony from Dr. Alan Donelson, a pharmacologist, to testify about the decedent's blood alcohol level at the time of the crash. Because of difficulties in obtaining a blood sample, the coroner instead relied upon a sample of vitreous humor, the clear fluid inside the eyeball. Dr. Donelson applied statistical equations to the result of this sample to calculate the decedent's blood alcohol level. On appeal, the plaintiff argued, inter alia, that the district court erred by failing to exclude Dr. Donelson's testimony, which the plaintiff asserted used an unreliable methodology. The Eighth Circuit disagreed, concluding that although this testimony was arguably not generally accepted, general acceptance was not a dispositive indicator of reliability and that Dr. Donelson's methodology satisfied Rule 702 and *Daubert*.

Key Language

- "At the end of the day, the jury appears to have believed Dr. Donelson's testimony, notwithstanding Ms. Olson's attacks. This does not suggest that something went 'wrong' or that the district judge should have excluded the testimony. Rather, it suggests that the adversary system worked exactly as it was supposed to. The jury weighed contradictory evidence and decided which evidence to credit." Olson, 481 F.3d at 626.
- "Neither Rule 702 nor *Daubert...* permits a district court to invade the province of the jury. Rule 702 does not permit a judge to weigh conflicting expert testimony, admit the testimony that he or she personally believes, and exclude the testimony that he or she does not personally believe. Nor does Rule 702 permit a judge to exclude expert testimony just because it seems doubtful or tenuous." *Id.*
- "The fact that two witnesses did not regard the formulas used by Dr. Donelson as reliable does not mean that testimony based on the formulas was inadmissible under Rule 702." *Id.* at 628.
- "More importantly, 'general acceptance' is now just one of multiple factors that a district court must consider in deciding whether to admit expert evidence under Rule 702. Ms. Olson could win the battle over general acceptance and still lose the war over admissibility." *Id.* at 628–29.

Hickerson v. Pride Mobility Prods. Corp. 470 F.3d 1252 (8th Cir. 2006)

Factual Summary

A widower lost his wife and his home in a house fire. He brought a products liability claim against the manufacturer of an electric motorized wheelchair, and a retailer, alleging that the wheelchair was defective and caused the fire. To support these claims, the plaintiff offered testimony from William L. Schoffstall, a cause and origin expert, who opined that the scooter was the origin of the fire and that the evidence indicated that the chair's wiring had experienced a fault. The district court partially granted the defendants' motion to exclude, concluding that Schoffstall could testify as to his investigation, but not that the chair was defective and caused the fire because, in part, such testimony had an unreliable methodology. The plaintiff appealed the exclusion of this testimony, which was needed to survive summary judgment. The Eighth Circuit reversed the partial exclusion of Schoffstall's testimony, stating, inter alia, that since he identified the point of origin for the fire and eliminated other potential causes, his methodology was sound.

Key Language

• "The methodology he used to generate his opinion is sound. He examined burn patterns, examined heat, fire, and smoke damage, considered this evidence in light of testimony regarding the fire, and identified a point of origin. He then considered as possible causes of the fire those devices that contained or were connected to a power source and that were located at the identified point of origin. He eliminated as possible sources those devices that were not in the area of origin or that were not connected to a power source and contained no internal power source. We can find nothing unreliable in this accepted and tested methodology." *Hickerson*, 470 F.3d at 1257.

Smith v. Cangieter 462 F.3d 920 (8th Cir. 2006)

Factual Summary

The estates of passengers killed during an automobile crash, along with the driver of another vehicle involved, sued the manufacturer, rental car company, and driver of the rented vehicle, alleging that the rented sport utility vehicle had design defects that caused the crash. The driver of the rented vehicle cross-claimed against the other defendants on similar grounds. To support their claims, the plaintiffs offered testimony from Dr. Richard Ziernicki, a mechanical engineer, who opined that the vehicle's four-wheel drive system created dynamic instability. The district court granted the defendants' motion in limine to exclude this testimony, finding that it lacked reliability because Ziernicki failed to test his theory, it was not peer-reviewed, and it had not been generally accepted. The plaintiffs appealed, arguing that the district court erred by focusing on Ziernicki's conclusions, rather than his methodology. The Eighth Circuit rejected this argument and concluded that Ziernicki's methodology was unreliable. Accordingly, it affirmed the district court's decision to exclude his testimony.

Key Language

 "[T]he plaintiffs and cross-claimant argue that the district court's analysis was legally flawed, because it focused on Ziernicki's conclusions rather than his methodology. But the Supreme Court has noted that 'conclusions and methodology are not entirely dis-

tinct from one another.' Where 'opinion evidence... is connected to existing data only by the ipse dixit of the expert,' a district court 'may conclude that there is simply too great an analytical gap between the data and the opinion proffered.' That is essentially the case here, where the agreed-upon fact that a loss of traction can occur with part-time four-wheel drive was simply not linked to the conclusion that the Pathfinder's four-wheel drive system was therefore unsafe at highway speeds. Ziernicki did not offer the results of any testing to demonstrate that his theory was accurate, and where there is no testing, there cannot be a known rate of error for the district court to consider. Ziernicki did not present accident data, produce tests performed by others, or perform his own mathematical calculations in an attempt to predict the effects of the loss of traction. His approach had not been scrutinized by the scientific community, and there were no peer-reviewed articles in support of his opinion." Smith, 462 F.3d at 924 (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)) (internal citation omitted).

Fireman's Fund Ins. Co. v. Canon U.S.A., Inc. 394 F.3d 1054 (8th Cir. 2005)

Factual Summary

The insurer of a strip mall brought a products liability action against a copier manufacturer, alleging that a design defect in one of its copiers caused a fire. To support this allegation, the plaintiff offered expert testimony from Beth Anderson and Michael Weld, purported fire causation experts. Specifically, Anderson and Weld opined that the copier's safety devices were improperly designed to prevent a fire. They reached this opinion after conducting a series of experiments where they bypassed certain safety components and demonstrated a temperature increase inside the copier, but not an open flame. The district court granted the defendant's motion to exclude this testimony as unreliable because their methodology did not comply with NFPA 921: Guide for Fire and Explosion Investigations. The Eighth Circuit agreed, holding that NFPA 921 provided a reliable methodology, but that Anderson and Wald did not reliably apply it. Accordingly, it affirmed the district court's decision to exclude their testimony.

Key Language

• "Anderson and Wald purportedly followed standards set forth by the National Fire Protection Association in its publication *NFPA 921: Guide for Fire and Explosion Investigations* (1998). This guide qualifies

- as a reliable method endorsed by a professional organization. However, *NFPA 921* requires that hypotheses of fire origin must be carefully examined against empirical data obtained from fire scene analysis and appropriate testing." *Fireman's Fund Ins. Co.*, 394 F.3d at 1057–58 (internal citations omitted).
- "Not only did the experimental testing fail to produce an open flame, but the experts were unable to explain the assumed heater control circuitry malfunction in theory or replicate it in any test. In short, the experimental testing of the heating element and thermal fuse in isolation did not establish that the thermal fuse would fail to prevent a fire caused by a heater control circuitry malfunction." *Id.* at 1058.
- "[N]either expert carefully examined this hypothesis of fire origin against empirical data obtained from fire scene analysis and appropriate testing, as required by NFPA 921.... Because the experts did not apply the principles and methods of NFPA 921 reliably to the facts of the case, the district court did not abuse its discretion in concluding that Anderson's and Wald's expert opinions were unreliable." *Id.* at 1059–60.

Meterlogic, Inc. v. KLT, Inc. 368 F.3d 1017 (8th Cir. 2004)

Factual Summary

The plaintiff corporation sued for damages claimed as a result of a failed contractual business arrangement between the parties. The district court granted summary judgment for the defendant corporation. The Eighth Circuit affirmed. Expert: Lawrence Redler.

Key Language

- "Given the nature of Redler's methodology, the district court concluded that his testimony was so unreliable as to be of no value to the finder of fact and therefore excluded it." *Meterlogic, Inc.*, 368 F.3d at 1020.
- "[A] study does not, in and of itself, allow Meterlogic to bootstrap Redler's expert opinion testimony into evidence when KLT has demonstrated substantial, legitimate problems with his methodology." *Id.*

Kudabeck v. Kroger Co. 338 F.3d 856 (8th Cir. 2003)

Factual Summary

In a slip and fall case, the district court denied the defendant store's motion in limine seeking to exclude the testimony of plaintiff's chiropractor. The defendant appealed from a jury verdict for the plaintiff. The Eighth Circuit affirmed. Expert: Dr. Brian Reilly (chiropractor).

Key Language

- "[O]nly where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable." *Kudabeck*, 338 F.3d at 862 (citing *Heller v. Shaw Indus.*, *Inc.*, 167 F.3d 146, 156 (3d Cir. 1999)).
- "[T]he district court did not abuse its discretion in admitting Dr. Reilly's opinion as reliable. Dr. Reilly based his opinion on his education, training, and proper chiropractic methodology and reason in treating [plaintiff] and forming an expert opinion." *Id.* at 864.

In re Air Crash at Little Rock, Ark. 291 F.3d 503 (8th Cir. 2002)

Factual Summary

An airline passenger sued the airline after suffering leg and knee injuries during a runway crash and later allegedly suffered from post-traumatic stress disorder ("PTSD"). The passenger offered testimony from a psychiatrist that passenger's PTSD was biological and not merely psychological, based on passenger's symptoms as well as research indicating that chronic PTSD leads to physiologically-based brain dysfunction. At trial, the airline objected that the psychiatric community does not recognize the theory that PTSD caused physical brain changes, and also that passenger has not shown any sufficient nexus between that theory and any physical condition in passenger's brain. The district court overruled the objections. After a jury verdict for the plaintiff, the airline appealed. The Eighth Circuit reversed, finding that the airline's objection was well founded. The plaintiff's psychiatrist, Dr. Harris, testified that medical tests exist that could determine whether passenger suffered from physical brain dysfunction. Because no doctor performed any such tests, no sufficient connection was established between psychiatrist's testimony and patient's condition. Moreover, testimony that passenger suffered from physical brain dysfunction should not be admitted unless supported by medical testing.

Key Language

"Daubert demands an assessment of whether the
expert's methodology has been tested, and an
inquiry into whether the technique has been subjected to peer review and publication, has a known
or knowable rate of error, and has been generally
accepted in the proper scientific community. We recognize that the district court has considerable lati-

tude in determining whether expert testimony will assist the trier of fact and be reliable, and it may consider one or all of the Daubert factors in making this determination." In re Air Crash, 291 F.3d at 514 (internal citation omitted).

- "Harris based his conclusion on plaintiff's disrupted sleep, lack of concentration and flashbacks. This was an inadequate foundation upon which to base the opinion that a physical change had taken place in plaintiff's brain." Id. at 515.
- "Instead, Fuller's testimony was based on his personal knowledge and observations of plaintiff at college both before and after the accident. This is more in the nature of a lay opinion testimony than expert testimony." Id.

United States v. Larry Reed & Sons P'ship 280 F.3d 1212 (8th Cir. 2002)

Factual Summary

An agricultural partnership and its individual partners were found by a jury to have submitted a false cotton crop insurance claim, in violation of the False Claims Act (FCA), and the partnership appealed. At trial, a government expert testified about the soil preparation of the partnership's farmland, based on his analysis of contemporaneous satellite imagery. The Eighth Circuit affirmed the district court's decision to admit this testimony, because the expert referenced hundreds of academic articles and discussed use of satellite imagery by NASA and universities to enhance agricultural productivity. The expert also testified regarding the application of this method in assessing crop damage. Expert: Dr. John Brown (soil preparation).

Key Language

- In evaluating the admissibility of the expert's testimony the Circuit Court found that "Brown referred to 'hundreds and hundreds' of academic articles published about the process of computer analysis of satellite images, the use of this method by NASA and about 10 major universities for the purpose of enhancing agricultural productivity, and the application of this method in assessing crop hail damage." Larry Reed & Sons P'ship, 280 F.3d at 1215-16.
- "Further, when testifying, Brown clearly explained his method of analysis, presented the satellite data, and illustrated how he applied the method to the facts before him. We conclude the district court did not abuse its discretion under Daubert and Kumho Tire when admitting Brown's expert testimony as reliable evidence." Id. at 1216.

Kinder v. Bowersox

272 F.3d 532 (8th Cir. 2001)

Factual Summary

A defendant convicted of rape and murder in state court filed a habeas petition challenging testimony from the prosecution's DNA expert. The defendant sought to exclude the testimony because the expert allegedly altered visual depiction of test results by erasing band that would have ruled out defendant, as well as other alleged methodological failings. The Eighth Circuit affirmed the district court's denial of the defendant's habeas petition. Specifically, the Eighth Circuit held that the trial court ruled consistently with *Daubert* in holding that the issue of alleged alteration of evidence was for jury and noted that Daubert does not bind state courts.

Key Language

 "The court further held that the methodology employed by the prosecution's expert, both in the DNA testing and in evaluating the results, was generally accepted by the scientific community. Therefore, challenges to the expert's methodology would again go to the weight and not the admissibility of the DNA evidence." Kinder, 272 F.3d at 545.

United States v. Boswell

270 F.3d 1200 (8th Cir. 2001), cert. denied, 70 U.S.L.W. 3640 (Apr. 15, 2002)

Factual Summary

A veterinarian involved in swine disease eradication program was convicted of two counts of making false statements to the government. On appeal, the defendant claimed that the prosecution did not lay a sufficient foundation for the reliability of polymerase chain reaction ("PCR") testing. The Eighth Circuit affirmed, noting that the expert correctly testified that the method is well-established and its reliability has been recognized by many courts. Although no written protocol was introduced, the expert testified as to procedures he followed in collecting the samples. Expert: Michael Spencer (scientist with Celera Aggen, a biotechnology company).

Key Language

• "This court previously held that any alleged deficiencies must so alter the PCR methodology as to make the test results inadmissible. Dr. Boswell failed to prove that there were significant deficiencies in the protocol and procedure used by Stormont Laboratories. Consequently, the alleged deficiencies go to the weight to be given the DNA evidence, not its admissibility. We, therefore, conclude that the district court did not abuse its discretion in admitting the government's DNA evidence." *Boswell*, 270 F.3d at 1205.

Glastetter v. Novartis Pharms. Corp. 252 F.3d 986 (8th Cir. 2001)

Factual Summary

A mother who suffered an intracerebral hemorrhage (ICH) after ingesting the drug Parlodel (bromocriptine) to suppress postpartum lactation brought products liability action against the drug manufacturer. The manufacturer moved to exclude mother's expert medical testimony and for summary judgment. The district court excluded causation testimony from the plaintiff's two physician experts and awarded summary judgment to the defendant. The Eighth Circuit affirmed this exclusion. Specifically, the Eighth Circuit stated that the differential diagnosis testimony was presumptively admissible unless scientifically invalid. Here, the physicians here lacked a scientific basis to "rule in" the defendant's medication as potential cause. Mere temporal association is insufficient, by itself, to show causation. The Eighth Circuit also found that the experts did not offer a sufficient basis for extrapolation from animal studies. Not only was each of these bases insufficient to "rule in" medication as potential cause of stroke; evidence was also insufficient to do so in the aggregate.

Key Language

- "In sum, the district court's gatekeeping role separates expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." Glastetter, 252 F.3d at 989.
- "Because a differential diagnosis is presumptively admissible, a district court may exercise its gatekeeping function to exclude only those diagnoses that are scientifically invalid. In the present case, the district court excluded the differential diagnoses performed by Glastetter's expert physicians because they lacked a proper basis for 'ruling in' Parlodel as a potential cause of ICH in the first place." *Id.* at 990.

J.B. Hunt Transp. v. Gen. Motors Corp. 243 F.3d 441 (8th Cir. 2001)

Factual Summary

An automobile passenger who had sustained catastrophic injuries in multi-vehicle accident brought suit against a trucking company. After entering settlement, the trucking company asserted crashworthiness claims against manufacturer of automobile and the compo-

nent seat manufacturer, alleging that seat defects had caused passenger's injuries. The district court excluded testimony from the truck company's accident reconstructionist. After a defense verdict, the truck company appealed. The Eighth Circuit affirmed the exclusion of this testimony, as the accident reconstructionist conceded his testimony was speculative. The Eighth Circuit also held that testimony from a "foamologist" was properly excluded, because: (1) his testimony was premised on reconstructionist's disallowed three-impact testimony; (2) "foamologist" had no formal training or course work in foam; and (3) "foamologist's" testimony was not derived from any scientifically reliable methodology.

Key Language

• "The testimony submitted by Sances was not derived from the application of any reliable methodology or scientific principle. It is well within the district court's 'discretion to choose among *reasonable* means of excluding expertise that is *fausse* and science that is junky." *J.B. Hunt Transp.*, 243 F.3d at 445.

Turner v. lowa Fire Equip. Co. 229 F.3d 1202 (8th Cir. 2000)

Factual Summary

A plaintiff was diagnosed with hyper reactive airway respiratory disorder following her exposure to discharge from a fire extinguisher at her place of employment. She brought a personal injury action against the fire equipment company that had inspected her employer's fire suppression equipment and that company brought a third-party action against the manufacturer of the fire extinguisher. The district court excluded causation testimony from her treating physician and awarded summary judgment to the defendant. The Eighth Circuit affirmed this exclusion, concluding that the plaintiff's physician did not apply a proper differential diagnosis. Expert: Dr. David Hof (specialist in pulmonary diseases).

Key Language

• "Most circuits have held that a reliable differential diagnosis satisfies *Daubert* and provides a valid foundation for admitting an expert opinion. The circuits reason that a differential diagnosis is a tested methodology, has been subjected to peer review/publication, does not frequently lead to incorrect results, and is generally accepted in the medical community." *Turner*, 229 F.3d at 1207–08.

• "Dr. Hof's causation opinion was not based upon a methodology that had been tested, subjected to peer review, and generally accepted in the medical community. Significantly, Dr. Hof did not systematically rule out all other possible causes. He was clearly more concerned with identifying and treating Delores's condition than he was with identifying the specific substance that caused her condition. Dr. Hof arrived at his opinion about baking soda more as an afterthought, in an ad hoc manner.... Therefore, although recognizing that a causation opinion based upon a proper differential diagnosis (one that systematically rules out other possible causes) satisfies Daubert, we conclude that the district court did not abuse its discretion in excluding Dr. Hof's particular causation opinion in this case." Id. at 1208.

EFCO Corp. v. Symons Corp. 219 F.3d 734 (8th Cir. 2000)

Factual Summary

EFCO Corporation ("EFCO"), brought suit against Symons Corporation ("Symons") for false advertising, misappropriation of trade secrets, and other business torts. Symons counterclaimed against EFCO for libel and for false advertising in violation of the Lanham Act. The jury returned verdicts in favor of EFCO on its claims and in favor of Symons on its claims. The district court reversed the jury's verdict on EFCO's claim of interference with prospective business relations, modified the remaining jury awards to account for duplication, and entered judgment for EFCO in the amount of \$14.1 million and in favor of Symons in the amount of \$50,000. The plaintiff's expert economist testified to damages, extrapolating from sales and financial data provided by both parties. The Eighth Circuit affirmed the admissibility of this testimony, as the expert's methods were not so unreliable as to require exclusion. Experts: Dr. John Hancock (forensic economics); Dr. Peter Orazem (economics).

Key Language

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• In evaluating the admissibility of the expert testimony the circuit court found that, "Hancock based his damage calculations on information he had received from EFCO and Symons regarding their revenue and on other information obtained from EFCO's Chief Financial Officer and United States Sales Manager. He focused on the panel leasing market, where EFCO and Symons were the only major competitors. From the leasing market shifts, Hancock extrapolated EFCO's past and future damages. Hancock's expert

testimony was not so unreliable as to be wholly excluded from jury consideration." 219 F.3d at 739.

Concord Boat Corp. v. Brunswick Corp. 207 F.3d 1039 (8th Cir.), cert. denied, 531 U.S. 979 (2000)

Factual Summary

Twenty-four recreational boat manufacturers brought an antitrust action against a stern drive engine manufacturer. The plaintiffs' economist relied on the Cournot model of economic theory, which posited that firms maximize profits by taking observed output of other firms as given and equating their own marginal costs and marginal revenues on that assumption. The economist applied this model by positing hypothetical market in which Brunswick has one competitor and concluding that any market share by Brunswick exceeding fifty percent must result in overcharges stemming from anticompetitive conduct. Jury returns verdict for plaintiffs. The Eighth Circuit concluded that the district court erred in admitting this testimony. Specifically, it stated that the district court appeared to have admitted the economist's testimony based in part on the plaintiffs' counsel's assurances that the economist's model would differentiate the effects of lawful competitive conduct from the effects due to unlawful antitrust violations, but the economist's model did not do so and departed from market realities. Accordingly, it reversed. Expert: Dr. Robert Hall (professor of economics at Stanford University).

Key Language

- "Dr. Hall's expert opinion should not have been admitted because it did not incorporate all aspects of the economic reality of the stern drive engine market and because it did not separate lawful from unlawful conduct. Because of the deficiencies in the foundation of the opinion, the expert's resulting conclusions were 'mere speculation." *Concord Boat Corp.*, 207 F.3d at 1057
- "Expert testimony that is speculative is not competent proof and contributes nothing to a 'legally sufficient evidentiary basis." Id.

Blue Dane Simmental Corp. v. Am. Simmental Ass'n 178 F.3d 1035 (8th Cir. 1999)

Factual Summary

The plaintiffs brought an action against a nonprofit corporation, alleging that the herdbook for Simmental breed of cattle included allegedly inaccurate registrations for certain cattle, in violation of Racketeer Influenced and Corrupt Organizations Act, Sherman Act, and Lanham Act, as well as asserting state law negligence claims. The district court granted judgment as a matter of law for the defendants. The Eighth Circuit affirmed and agreed that the exclusion of the plaintiffs' expert testimony was not an abuse of discretion. Expert: Dr. Alan Naquet (agricultural economist).

Key Language

- "Although the before and after method of analysis used by the expert was typical within his field, that method was not typically used to make statements regarding causation without considering all independent variables that could affect conclusions." *Blue Dane Simmental Corp.*, 178 F.3d at 1035.
- Dr. Baquet stated that generally "an economist would attempt to identify and evaluate all of the independent variables significantly affecting changes in the value of a breed. Dr. Baquet acknowledged that he had neglected to consider any variables other than the introduction of the Risinger fullbloods." *Id.* at 1040.

In re Viagra Prods. Liab. Litig. 658 F. Supp. 2d 950 (D. Minn. 2009)

Factual Summary

In multi-district proceedings, consumers brought actions against a drug manufacturer alleging that its drug, Viagra, caused them to suffer vision loss. To support their claims, the plaintiffs offered testimony from five specific causation witnesses, as well as a purported regulatory expert. The defendant challenged each of these witnesses, arguing that the specific causation experts conducted a methodologically flawed differential diagnosis opinion and that the plaintiff's regulatory expert, inter alia, relied on inapplicable Food and Drug Administration guidelines and was irrelevant. After discussing each witness' opinion and methodology, the district court granted the defendant's motions to exclude the specific causation opinions and granted-in-part the motion to exclude the plaintiffs' regulatory expert.

Key Language

• "'[A] medical opinion about causation, based upon a proper differential diagnosis, is sufficiently reliable to satisfy *Daubert*.' However, a differential diagnosis that fails 'to consider all the possible causes, or to exclude each potential cause until only one remain[s], or to consider which of two or more nonexcludable causes [is] the more likely to have caused the condition' is not a proper differential diagnosis to determine causation, and a causation opinion based

- on that inadequate methodology is not admissible to show causation. Differential diagnoses are presumptively admissible and a court therefore only excludes scientifically invalid diagnoses." *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d at 957 (quoting *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000)) (alterations in original).
- "Daubert clearly envisioned a greater role for a trial judge than simply rubberstamping any expert who could say that he held opinion to a reasonable degree of medical certainty after reviewing all of the evidence." *Id.* at 959.
- "Common sense and Federal Rules of Evidence 702 require the exclusion of any expert opinion that was reached prior to conducting the research necessary to form that opinion." *Id.* at 963.
- In a prior opinion, the court also noted that an expert's attempt to remedy litigation-driven analysis by relying on a previously conducted study was inadequate, concluding that the fact that the expert waited to disclose it until after his opinions had been challenged in litigation was insufficient, because "the fact that [the study and "reanalysis"] were produced in response to concerns raised in this litigation" resulted in "the Court find[ing] that [they] do not form a reliable basis under *Daubert* on which [the expert] can form an admissible general causation opinion in this litigation." *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936, 945 (D. Minn. 2009).

Cummings v. Deere & Co. 589 F. Supp. 2d 1108 (S.D. Iowa 2008)

Factual Summary

A farmer brought an action against a combine manufacturer, alleging that a defect in the combine's fuel tank caused a fire. To support this claim, the plaintiff offered testimony from Dr. Charles Roberts, who conducted an investigation into the fire shortly after it occurred. At that time, he concluded that the fire was caused by fuel leakage, but could not conclude what caused this leakage or how it was ignited. After litigation commenced, Dr. Roberts prepared a second report to "refine" his prior conclusions. In this report, he now concluded that the fuel leak was caused by electrostatic discharge. He stated that this change was based on work he conducted in other litigation. Later, he provided a rebuttal report that added information based on a critique from the defendant's expert. The defendant challenged Dr. Roberts' opinions as based on a flawed and unscientific methodology. The district court agreed, concluding that several Daubert factors sug-

gested it was unreliable. Particularly notable, according to the court, was the fact that Dr. Roberts rendered his primary opinion without having sufficient information or making the necessary calculations to make it reliable, that he modified it as the litigation progressed, and that he failed to rule out or consider alternative explanations. Thus, the court determined that Dr. Roberts did not use reliable principles and methods to render his conclusion and excluded his testimony.

Key Language

• "Performing calculations and belatedly considering variables which an opposing expert correctly points out you did not do or know, and which you admitted you did not do or know, is not rebuttal—it is clearly the interjection of new opinion evidence. In this Court's view, such tactics weigh heavily in favor of finding that Dr. Roberts' opinions are not reliable, and are, in fact, a results-driven product of litigation. Dr. Roberts' belated attempts to create a scientific basis for his opinions are a tacit admission on his part that his opinions were not properly founded when they were formed." Id. at 1115-16.

In re Baycol Prods. Litig. 532 F. Supp. 2d 1029 (D. Minn. 2007)

Factual Summary

In multi-district proceedings, patients brought actions against manufacturers of a prescription drug to treat high cholesterol, claiming that the drug caused them cardiovascular harm, other damage, or sought medical monitoring. The defendants filed a motion to exclude ten of the plaintiffs' medical experts and the plaintiffs filed a motion to exclude, in part, the testimony of the defendants' regulatory expert. The court granted all of the defendants' motions, with some qualifications, and denied the plaintiffs' motion after discussing each expert, as well as his or her opinion, its bases, and its methodology. Generally, the court noted improper reliance on Adverse Event Reporting System data, lack of testing, and lack of peer review or publication as common factors amongst the inadmissible opinions from the plaintiffs' experts.

Key Language

- "Failure to show the reliability of each step in an expert's methodology is fatal under Daubert." In re Baycol Prods. Litig., 532 F. Supp. 2d at 1042.
- "It is generally accepted that bias in the conduct of a study can materially affect the result and that detection and accounting for bias are standard tools of epidemiology." Id. at 1043.

- "[T]o recalculate a study, based in part on an unreliable methodology, would render the recalculation unreliable." Id. at 1046.
- "The Eighth Circuit has cautioned against expert opinions that are 'reasoned from an end result in order to hypothesize what needed to be known but was not." Id. at 1046 (quoting Sorensen v. Shaklee Corp., 31 F.3d 638, 649 (8th Cir. 1994)).
- "[E]xpert testimony that is merely speculation or pure conjecture based on the expert's impressions of the physical evidence must be excluded as not based on any reliable methodology or scientific principle." Id. at 1053.
- · "An expert may rely on inferences, analogies and extrapolation as long as the gap[] between steps is not too great." Id. at 1056.
- "Animal studies can also form the basis for an opinion if they are interpreted with the proper care and precision.... The Eighth Circuit has recognized that because of the dose-response differential between animals and humans, extrapolating to humans from animal studies can be problematic. Expert opinion testimony has been excluded when the expert fails to take into account the critical differences in animal data and human experiences, including but not limited to extrapolation in dosing." Id. at 1065 (internal citation omitted).

Schwab v. Nissan N. Am., Inc. 502 F. Supp. 2d 980 (E.D. Mo. 2007)

Factual Summary

The driver of a vehicle that rolled over during a crash brought a products liability action against the vehicle's manufacturer and seller, alleging that its roof was prone to collapse during foreseeable rollovers. The plaintiff offered testimony from three purported experts, Donald Friedman, Dr. Jack Bish, and Dr. George Rechnitzer, to substantiate these allegations. Their opinions relied on two sets of testing they performed: a "two-sided" test, where a hydraulic ram pressed a steel plate against an exemplar vehicle's roof, and the "Jordan Rollover System" test, where an exemplar, or a portion thereof, was suspended over a purported simulated road surface, rotated, and then lowered onto the surface. The defendants filed motions to exclude both of these tests and the opinions that relied on them. The court granted these motions. Specifically, the court determined that, although it had some similarities with testing required by the Federal Motor Vehicle Safety Standards, the "two-sided" test was unreliable because it inappropriately concentrated

force on a small section of the vehicle's roof, had never been validated, had not been subjected to meaningful peer review, and was not accepted by any other experts in the automotive industries. The court also determined that the Jordan Rollover System test was inadmissible because its parameters were arbitrary and not based on reliable scientific principles and methodology, it had not been subjected to meaningful peer review, and it had not been accepted by any automotive engineering entity. Thus, the court determined that these tests, as well as all opinions from the plaintiff's experts that relied on them, must be excluded.

Key Language

- "Validation requires a more rigorous scientific analysis than the 'I say it's valid, therefore it must be valid' statement from an expert. To satisfy the reliability requirement plaintiffs must establish by a preponderance of the evidence that the methodology is *scientifically* valid. That requirement includes a showing that the methodology is generally applied properly to the facts at issue in this case based on *scientifically accepted methodology.*" *Schwab*, 502 F. Supp. 2d at 985 (internal citation omitted).
- "[T]he 'two-sided' test is not based on reliable scientific principles and methodology. The two-sided test has never been validated, it has not been subjected to meaningful peer review and it has not been accepted by any other experts or entities within the automotive engineering industry." *Id.* at 985–86.
- "The [Jordan Rollover System] test parameters may reflect the 'best guess' of the proffered experts but the test parameters are not the result of any identifiable scientific methodology." *Id.* at 986.
- "[T]he [Jordan Rollover System] test is not based on reliable scientific principle and methodology. The [Jordan Rollover System] test has never been validated. It has not been subjected to meaningful peer review and it has not been accepted by any automotive engineering entity. As a result the [Jordan Rollover System] test and all opinions based on the test will be excluded pursuant to Federal Rule of Evidence 702." *Id.* at 988.

Schipp v. Gen. Motors Corp. 433 F. Supp. 2d 1023 (E.D. Ark. 2006)

Factual Summary

The driver of a vehicle who caused a crash brought a cross-claim against the vehicle's manufacturer, alleging that a defect in the vehicle's torsion bar adjuster, part of the suspension system, was defective. The plain-

tiff retained Dr. Jahan Rasty and Dr. Dale Wilson, who opined that a manufacturing or material defect in the torsion bar adjuster caused it to fracture and lead to the crash. Rasty's opinion was based primarily on a visual observation of the vehicle. Wilson conducted limited testing, but relied on his experience for key aspects of his opinion. The district court granted the defendant's motion to exclude their testimony, concluding that their opinions lacked a reliable methodological foundation, as they failed to conduct appropriate testing, did not apply generally accepted methodology, and made unwarranted and speculative assumptions. Accordingly, the court excluded both Rasty and Wilson's testimony.

Key Language

- The court noted that the American Society for Metal ("ASM") Handbook, *General Practice in Failure Analysis*, outlined the "principal stages of a failure investigation and analysis" and that "these steps define the general practice in failure analysis and represent a reliable method of failure investigation and analysis." *Schipp*, 433 F. Supp. 2d at 1028.
- "For purposes of the *Daubert* motion, the important point is not that Rasty's opinion was wrong; the important point is that he did not do the chemical analysis that could confirm or disconfirm his theory. That analysis is one of the steps in general practice in failure analysis, according to the ASM Handbook." *Id.* at 1029.
- "To summarize, Rasty's opinions rest largely on visual examination. General practice in failure analysis, as reflected in the ASM Handbook, requires further testing. In this instance, such testing would include chemical analysis of the materials on the fracture surface using scanning electronic microscope analysis, metallographic sectioning, and testing under simulated conditions to see whether a fractured torsion bar adjuster would support the weight of the vehicle. Rasty performed none of these tests. In essence, he adopted a hypothesis but failed to test it. His opinions are therefore unreliable." *Id.* at 1031.

Medalen v. Tiger Drylac, U.S.A., Inc. 269 F. Supp. 2d 1118 (D. Minn. 2003)

Factual Summary

The plaintiff filed a products liability action against the defendant manufacturer, alleging development of skin cancer as a result of exposure to paints. The defendant moved for summary judgment and challenged the plaintiff's experts' opinions as inadmissible. The district court granted the motions. Expert: Dr. Martinez (toxicologist).

Key Language

• "We claim no expertise in toxicology, but we are convinced that Dr. Martinez applied no recognized methodology in reaching his causation opinion, much less a scientific one." Medalen, 269 F. Supp. 2d at 1135.

Waitek v. Dalkon Shield Claimants Trust 934 F. Supp. 1068 (N.D. Iowa 1996)

Factual Summary

The manufacturer of Dalkon Shield intrauterine device (IUD) filed postrial motions for judgment as matter of law, for new trial, and for remittitur after jury awarded user of Dalkon Shield compensatory damages in their products liability action. The district court denied the defendant's motions. Expert: Dr. R. Bruce Dunker (gynecologist).

Key Language

• "Expert's opinion that plaintiff's use of Dalkon Shield intrauterine device (IUD) was cause of her injuries was not based on novel scientific test or unique controversial methodology or technique, but rather was based on his experience in training as both gynecologist and as doctor experienced in use of and medical problems associated with Dalkon Shield, and thus factors outlined in Daubert for admissibility of scientific evidence were not applicable." Waitek, 934 F. Supp. at 1068.

Ninth Circuit

Primiano v. Cook 598 F.3d 558 (9th Cir. 2010)

Factual Summary

A patient brought a products liability action against a medical device manufacturer, as well as other individuals, alleging that a defective artificial elbow caused her to sustain injuries and health complications. The plaintiff proffered the testimony of Dr. Arnold-Peter Weiss to support her claim, who opined that the lifespan of the artificial elbow she received was unusually short. The district court granted the defendants' motion to exclude Dr. Weiss' testimony, concluding, inter alia, that it did not meet Daubert due to the lack of peer review and publication, and that Dr. Weiss appeared to conclude that merely because there had been rapid wear in the device, it must have been defective, rather than considering other potential causes such as medical malpractice. The Ninth Circuit reversed and held that Dr. Weiss'

testimony was admissible. Specifically, the Ninth Circuit found that in many medical cases, due to the fact that the field of medicine is often experience-based, a medical expert's methodology is reliable if it compares the plaintiff's experience with what medical professionals with specific expertise in that area typically observe, combined with a familiarity with the relevant peerreviewed literature. Because Dr. Weiss followed this methodology, the court held that his testimony was admissible and that the district erred by excluding it.

- "Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." Primiano, 598 F.3d at 564.
- "Lack of certainty is not, for a qualified expert, the same thing as guesswork." Id. at 465.
- "We have some guidance in the cases for applying Daubert to physicians' testimony. 'A trial court should admit medical expert testimony if physicians would accept it as useful and reliable,' but it need not be conclusive because 'medical knowledge is often uncertain.' 'The human body is complex, etiology is often uncertain, and ethical concerns often prevent double-blind studies calculated to establish statistical proof.' Where the foundation is sufficient, the litigant is 'entitled to have the jury decide upon [the experts'] credibility, rather than the judge." Id. at 565–66 (quoting *United States v. Sandoval-Mendoza*, 472 F.3d 645, 654 (9th Cir. 2006)) (internal footnotes omitted) (alterations in original).
- "His methodology, essentially comparison of what happened with Ms. Primiano's artificial elbow with what surgeons who use artificial elbows ordinarily see, against a background of peer-reviewed literature, is the ordinary methodology of evidence based medicine: 'not a science but a learned profession deeply rooted in a number of sciences,'... and 'rel[ying] on judgment—a process that is difficult to quantify or even to assess qualitatively. Especially when a relevant experience base is unavailable, physicians must use their knowledge and experience as a basis for weighing known factors along with the inevitable uncertainties' to 'mak[e] a sound judgment." Id. at 567 (quoting Cecil Textbook of Medicine 1 (James B. Wyngaarden & Lloyd H. Smith Jr. eds., 17th ed. 1985); Harrison's Principles of Internal Medicine 3 (Dennis L. Kasper et al. eds., 16th ed. 2005)) (internal footnotes omitted) (second and third alterations in original).

United States v. Sandoval-Mendoza 472 F.3d 645 (9th Cir. 2006)

Factual Summary

The defendant and his brother were convicted of conspiring to sell drugs. The defendant argued entrapment and contended, among other things, that the district court erred in excluding expert testimony that would have supported his contention that brain damage resulting from a tumor made him vulnerable to entrapment. The district court concluded that the medical expert opinion was unreliable because it lacked scientific validity and was insufficient for the use it was proffered. The Ninth Circuit found that district court erred in excluding this testimony because the district court required the defendant's experts to establish conclusive proof that the defendant's brain tumor made him susceptible to inducement. In the Ninth Circuit's opinion, however, medical knowledge is often uncertain and opinions cannot always be tested, thus proffered expert testimony should be admissible when the medical knowledge permitted the expert to offer a reasonable, albeit not conclusive, opinion. Thus, the Ninth Circuit reversed.

Key Language

- "When evaluating specialized or technical expert opinion testimony, 'the relevant reliability concerns may focus upon personal knowledge or experience.' Because medical expert opinion testimony 'is based on specialized as distinguished from scientific knowledge, the *Daubert* factors are not intended to be exhaustive or unduly restrictive.'... [T]he district court 'applied an inappropriately rigid *Daubert* standard to medical expert testimony' by not accepting what 'a good [physician] would in determining what is reliable knowledge in the [medical] profession." *Sandoval-Mendoza*, 472 F.3d at 655 (quoting *Sullivan v. U.S. Dep't of the Navy*, 365 F.3d 827, 833–34) (internal footnotes omitted) (second and third alterations in original).
- "A trial court should admit medical expert testimony if physicians would accept it as useful and reliable. Utility to the jury of medical expert testimony should be determined by what physicians would accept as useful.... [M]edical knowledge is often uncertain. The human body is complex, etiology is often uncertain, and ethical concerns often prevent double-blind studies calculated to establish statistical proof. This does not preclude the introduction of medical expert opinion testimony when medical knowledge 'permits the assertion of a reasonable

opinion." *Id.* at 655 (quoting *United States v. Finley*, 301 F.3d 1000, 1007 (9th Cir. 2002)).

Swirsky v. Carey

2004 U.S. App. LEXIS (9th Cir. July 12, 2004)

Factual Summary

The plaintiff songwriters sued defendants for copyright infringement. The district court granted summary judgment. The appellate court reversed the grant of summary judgment. Expert: Dr. Walser (musicologist).

Key Language

• "There is nothing unsound about Dr. Walser's methodology in this case. The district court is correct that [the] methodology is 'selective....' Dr. Walser, however, explained that the melody... and bassline of a song canot be divorced from the harmonic rhythm of a song." *Swirsky*, 2004 U.S. App. LEXIS, at *13.

United States v. Finley

301 F.3d 1000 (9th Cir. 2002)

Factual Summary

The defendant owned a law bookstore and ran a bar review course for students from unaccredited law schools. The defendant was indicted on several counts, including bank fraud, relating to his attempts to negotiate instruments he had been repeatedly told were fraudulent. He tried to introduce expert testimony that he had a mental condition that would negate the intent requirement of fraud. The district court initially allowed the expert to testify that the defendant had a delusional disorder, but later struck the testimony upon a motion from the government. The defendant was then convicted. The Ninth Circuit reversed. Expert: Dr. John J. Wicks (clinical psychologist, testifying to the defendant's mental condition to show lack of criminal intent).

- "It appears from the record before us that Dr. Wicks based his diagnosis on proper psychological methodology and reasoning. He relied on accepted psychological tests... and he took a thorough patient history, including meeting with [defendant's] wife and observing [defendant's] behavior. Dr. Wicks did not base his conclusions solely on [defendant's] statements; rather, he used his many years of experience and training to diagnose [the] mental condition." *Finley*, 2002 WL 1902249, at *7.
- The court also noted that the expert "did not use any experimental techniques" and "did not deviate in

- any way from his normal practice of conducting psychological evaluations." Id.
- Further, the court found no merit to the government's argument that Dr. Wicks' opinion was "founded" upon a belief that the defendant was truthful. The key, the court concluded, was that "Dr. Wicks did not merely recite [defendant's] statements to the jury in the guise of a medical opinion." *Id.* at *8.

United States v. Hermanek 289 F.3d 1076 (9th Cir. 2002)

Factual Summary

The defendants were convicted of drug-related offenses. As part of the case, the government introduced the expert testimony of Agent Broderick, who interpreted many of the intercepted telephone conversations that were used against the defendants. On appeal, the defendants argued that the government failed to establish a basis for Agent Broderick's interpretation of words and phrases that he had not previously encountered as referring to cocaine. The Ninth Circuit found that the government had not established that his interpretation of new drug terminology was based upon reliable methods, but found that any error on the part of the district court was harmless. Expert: John Broderick (FBI Special Agent, on interpretation of words used in drug trade).

Key Language

- The government's "offer of proof" relating to Agent Broderick's expertise "describes only Broderick's method for interpreting words 'commonly used' in the drug trade... [i]t therefore offers no basis for assessing the reliability of Broderick's interpretation of words and phrases encountered for the first time in this case." Hermanek, 289 F.3d at 1093.
- "The district court relied solely on Broderick's general qualifications without requiring the government to explain the method Broderick used to arrive at his interpretations of words he had never encountered before. This was error." Id. at 1094.

Domingo v. T.K. 289 F.3d 600 (9th Cir. 2002)

Factual Summary

The plaintiff brought a medical malpractice action, alleging that as a result of hip surgery, he suffered brain damage. The expert's theory was that, as a result of the defendant doctor requiring one hour and ten minutes (as opposed to the usual 3-15 minutes) to "mallet" the plaintiff's prosthesis into place, excess fat

particles were released into the plaintiff's system causing severe brain damage. The defendant's experts testified that although the plaintiff's condition was a known risk of hip replacement surgery, there was no consensus as to why the condition occurs and no belief that prolonged exposure to "malleting" would lead to such a condition. The district court, relying in part on the recommendation of a technical advisor, excluded the plaintiff's expert's testimony, finding that it was based on an inadequate methodology. The Ninth Circuit affirmed. Expert: Dr. Kevin Harrington (orthopedic expert physician, on causation of brain damage due to a surgical procedure).

Key Language

- "Scientific evidence is deemed reliable if the principles and methodology used by the expert proffering it are grounded in the methods of science." Domingo, 289 F.3d at 605.
- Experts may demonstrate scientific validity of their conclusions "by showing that 'the research and analysis supporting the proffered conclusion have been subjected to normal scientific scrutiny through peer review or publication," or "by explaining 'precisely how [the experts] went about reaching their conclusions and point[ing] to some objective source... to show that they have followed the scientific method...." Id. at 606.
- Where "no theory linking extensive malleting to [plaintiff's condition] has ever been published," the expert "did not establish that the studies he use[d] to support his theory [were] applicable to human operations," and where the expert failed to set forth in any manner that a prolonged malleting process increases the risk of the plaintiff's condition beyond the increased risk created by hip surgery in the first place, the expert's testimony was not "based on objective, verifiable evidence and scientific methodology of the kind typically used by experts in the field." Id. at 606-07.

Metabolife Int'l v. Wornick 264 F.3d 832 (9th Cir. 2001)

Factual Summary

The plaintiff, a manufacturer of herbal supplements, sued a Boston television station, a reporter, and the doctor whom the reporter interviewed for defamation following a news story in which the defendants suggested that the plaintiff's product was unsafe. The plaintiff sought to introduce expert witnesses that its product was safe if used as directed. This included: (1) five experts opining based upon "scientific risk assessment;" (2) Dr. Ruth Hammel Strauss's interpretation of an unpublished study she had performed at Columbia Medical Center; (3) animal toxicity tests performed in China; and (4) short-term efficacy studies conducted at Vanderbilt University Medical Center and St. Luke's-Roosevelt Hospital Center. The district court excluded all of this evidence, finding it too unreliable and lacking explanation of methodology. The Ninth Circuit reversed in part, finding that the Chinese animal studies and unpublished Columbia University study should have been considered and that the district court needed to re-address the admissibility of the risk assessment evidence, but affirmed with respect to the short-term efficacy studies. Expert: Dr. Ruth Hammel Strauss (cardiovascular medicine, efficacy of herbal supplements).

Key Language

- "While regulation of experimentation in the United States may bolster the reliability of results generated domestically, there is no reason to assume that experimentation abroad either would not meet those regulations or is unreliable despite deviancies." *Wornick*, 264 F.3d at 843.
- The district court excluded the unpublished Columbia study because it was incomplete and because it was commissioned by the plaintiff. The Ninth Circuit said these inquiries are not related to methodology: "Rather than disqualify the study because of 'incompleteness' or because it was commissioned by Metabolife, the district court should examine the soundness of the methodology employed." *Id.*
- "Metabolife's experts explained the process of risk assessment and pointed to objective sources.... Examining the declarations of the scientists who prepared the risk assessments... the declarations explain the methodology of risk assessment and how the data found in peer-reviewed articles and adverse incident reports was used" and thus should not have been summarily dismissed by the district court. *Id.* at 845.

Kennedy v. Collagen Corp. 161 F.3d 1226 (9th Cir. 1998)

Factual Summary

A husband and wife sued a manufacturer of a medical product used to treat facial wrinkles for negligence, product liability, breach of warranty, battery, and conspiracy. The plaintiff wife alleged that she contracted lupus as a result of injections of the defendant's product. The plaintiffs sought to introduce the opinion of Dr. Spindler that the defendant's product caused auto-

immune disorders, such as lupus. Dr. Spindler relied on peer-reviewed articles, studies, and trials conducted by the defendant, and on examinations of the plaintiff. The district court rejected the testimony, finding that it lacked scientific reasoning. The Ninth Circuit reversed. Expert: Dr. Joseph Spindler (rheumatologist, causation of plaintiff's injuries due to use of medical product).

Key Language

- The appeals court criticized the district court for focusing too much on the lack of employed by the expert. "Ultimately, the trial court failed to distinguish between the threshold question of admissibility... and the persuasive weight to be accorded such testimony by a jury." *Kennedy*, 161 F.3d at 1228.
- "The fact that a cause-effect relationship between [defendant's product] and lupus... has not been conclusively established does not render Dr. Spindler's studies backing up the expert's opinion and not enough on the actual methodology testimony inadmissible." *Id.* at 1230.
- "Dr. Spindler's analogical reasoning was based on objective, verifiable evidence and scientific methodology of the kind traditionally used by rheumatologists. This is precisely what *Daubert* requires." *Id*.

Salinas v. Amteck of Ky., Inc. 682 F. Supp. 2d 1022 (N.D. Cal. 2010)

Factual Summary

Construction workers at a winery were injured, one fatally, when the scissor lift on which they were working tipped over. The plaintiffs brought action against the contractors and manufacturer of the scissor lift, asserting, inter alia, that the manufacturer failed to adequately warn of the dangers of tip-overs and load limitations. To support this claim, the plaintiffs offered the testimony of Gerald Fulghum, a safety engineer, who opined that applicable warnings were insufficient, ambiguous, and should have included a pictogram for non-English speaking workers. As part of a motion for summary judgment, the manufacturer incorporated a Daubert challenge directed at Fulghum's testimony, arguing, in part, that his opinions had not been tested, were litigation-driven, and were not reliable. The court agreed and found the plaintiffs had not met their burden of establishing that Fulghum's opinions were admissible. Specifically, the court found that Mr. Fulghum's testimony was not based on reliable principles and methods because he had no legitimate, objective scientific basis for his opinions, nor had he conducted any testing

or peer consultation. As a result, the court excluded his opinion and granted the manufacturer's motion.

Key Language

- "Scientific evidence is reliable if it is based on an assertion that is grounded in methods of science—the focus is on principles and methodology, not on conclusions." *Salinas*, 682 F. Supp. 2d at 1030.
- "[T]he trial court should be mindful that reliability is not determined based on the 'correctness of the expert's conclusions but the soundness of his methodology." *Id.* (quoting *Stilwell v. Smith & Nephew, Inc.*, 482 F.3d 1187, 1192 (9th Cir. 2007)).
- "While [Mr. Fulgham's] opinions are not based on scientific experimentation, they must have some objective scientific basis to which he may apply the facts of the case. However, the evidence does not reflect that he employed a methodology that would allow him to opine as an expert on warnings, as he testified that he never inspected the subject scissor lift; never looked at photos of the scissor lift to determine what safety labels it contained; never inspected the accident scene; never saw the platform rating placard on the scissor lift that stated that there was an allowable side pull of 100 pounds; relied on a generic safety manual to infer what warnings might be on the subject scissor lift; never reviewed [the defendant's expert's] declaration that was submitted in support of the present motion; and never talked to Reynaldo Salinas about what Reynaldo could or could not derive from the manuals or warning/safety labels on the scissor lift." Id.

McClellan v. I-Flow Corp.

710 F. Supp. 2d 1092, 2010 WL 1753261 (D. Or. 2010)

Factual Summary

Several patients brought product liability actions against pain pump manufacturers, alleging that they developed chondrolysis in their shoulders after pain pumps were used to administer local anesthetics during and/or after arthroscopic surgery. The defendants moved to exclude the general causation testimony of nine of the plaintiffs' expert witnesses. Specifically, the defendants argued, in part, that the plaintiffs' experts' opinions were based on a flawed methodology that erroneously "ruled in" the pain pumps as the cause of chondrolysis, even though there was insufficient data to support this assertion. Although the court partially granted the motions with respect to specific experts, it denied the general motion to exclude their general causation testimony, concluding that the use of a differential diagnosis in this situation

was appropriate and that it had been properly conducted by the plaintiffs' experts.

- "[T]he proper focus under *Daubert* is whether an expert's testimony rests on evidence reliably derived from scientific methodology and is relevant to the facts of the case, not whether plaintiffs' experts can *prove* the point of their testimony." *McClellan*, 2010 WL 1753261, at *8.
- "Unlike the majority of cases in which differential diagnosis was held insufficient to rule in a potential causative factor, plaintiffs here do not allege toxic exposure through air, water, or groundwater contamination, or through the ingestion of a pharmaceutical drug.... In such cases, a whole host of potential causal factors—medical, environmental, occupational—may be implicated, such that the connection between the accused product and resulting injury is not readily apparent, if not tenuous. Depending on the specific facts of alleged injury and the relevant evidence cited to support causation, the differential diagnosis methodology might well be inappropriate and insufficient to reach Daubert's reliability threshold for general causation.... In contrast,... not only does a direct physical correlation exist between the point of exposure and the resulting injury to the shoulder joint, there is an appreciable temporal relationship between the exposure to continuous infusion and the development of chondrolysis." Id. at *9-10.
- "Defendants maintain that plaintiffs' experts cannot reliably extrapolate data from these in vitro and animal studies to demonstrate causation in humans, particularly when the findings of the studies do not espouse a causal connection between continuous infusion and chondrolysis.... However, 'analogy, inference and extrapolation can be sufficiently reliable' when the expert's opinion is the 'kind that a reasonable scientist or physician would make in a decision of importance arising in the exercise of his profession outside the context of litigation." *Id.* at *16 (quoting *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181, 189 (S.D. N.Y. 2005)).
- "I thus find that reliance on and reference to the totality of medical evidence is a valid methodology, and that the evidence cited by plaintiffs' experts sufficiently, even if not conclusively, supports their opinions.... The methodologies of plaintiffs' experts hardly reach the outer boundaries of medical knowledge to justify exclusion of their testimony." *Id.* at *21.

- "Most of plaintiffs' experts adopt similar methodologies: reliance on their knowledge and clinical experience combined with review of the relevant medical literature and, in most cases, medical records of patients with chondrolysis. I find that such methods are generally accepted in the medical field." *Id.* at *22.
- "Daubert counsels against rigid formulations of reliability and instead requires the court to carefully examine plaintiffs' experts' methodologies as applied to the specific facts presented, remaining mindful that plaintiffs' ultimate burden is proof by a preponderance of the evidence." Id. at *44.

Rodriguez v. Gen. Dynamics Armament & Tech. Prods., Inc. 696 F. Supp. 2d 1163, 2010 WL 932364 (D. Haw. Mar. 11, 2010)

Factual Summary

A mortar cartridge prematurely exploded during an Army training exercise, killing two soldiers and injuring two others. The injured soldiers and the estates of the soldiers who died brought a claim against the defense contractor, alleging that the mortar was defectively manufactured. To support this claim, the plaintiffs offered testimony from John R. Nixon, a mechanical engineer. After reviewing witness statements, depositions, and the Army's investigation report, Nixon opined that the explosion was caused by one of three possible defects. The defendant moved to exclude this testimony, arguing, inter alia, that his opinions were unreliable because he did not perform independent research, attempt to test his theories, and did not perform an on-scene inspection. The district court disagreed. It found that Nixon's opinions were sufficiently reliable given the unique circumstances of the case, since testing and other measures were limited given the destruction of the mortar at issue when it exploded and the Army's exclusive possession of similar mortars. As a result, given the circumstances, the court found that his opinions were based on an appropriately reliable methodology.

Key Language

 "Testing of the opinion of any expert in this case, peer review, or a calculation of error-rate are procedures all hampered by the destruction of the mortar in question. To complicate matters, the Army has exclusive possession of the remaining mortars. Under these circumstances, an expert may reasonably base an opinion regarding the cause of the premature explosion on theoretical possibilities or on previous experience with similar ammunition." *Rodriguez*, 2010 WL 93264, at *9.

Henricksen v. ConocoPhillips Co. 605 F. Supp. 2d 1142 (E.D. Wash. 2009)

Factual Summary

A former gasoline tanker truck driver and his wife brought a products liability claim against his former employer, a gasoline company, alleging that his occupational exposure to benzene and benzene products, including gasoline, caused his leukemia. The gas company moved to exclude the plaintiffs' purported causation experts, arguing that their methodology had no scientific basis, was unreliable, was not supported by material facts of this case or by reliable studies, and had not been tested or peer reviewed. The court granted the defendant's motion, concluding that these experts employed a flawed methodology that lacked scientific support, did not account for alternative possibilities, and used analysis based on speculation and erroneous data. Accordingly, the court excluded it.

- "Something doesn't become scientific knowledge just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were derived by the scientific method be deemed conclusive." *Hendricksen*, 605 F. Supp. 2d at 1154.
- "[I]t is not always necessary for a plaintiff to quantify exposure levels precisely or use the dose-response relationship, provided that whatever methods an expert uses to establish causation are generally accepted in the scientific community. While precise or exact information concerning dosage or the dose-response relationship is not always required, the boundaries of allowable expert testimony are not so wide as to permit an expert to testify as to specific causation without having any measurements of a plaintiffs' exposure to the allegedly harmful substance." *Id.* at 1157.
- "Differential diagnosis is the process of elimination that physicians routinely use to identify the 'most likely' cause of a particular individual's illness. It is an acceptable source of data on specific causation. By examining the patient's symptoms, medical history, diagnostic test results, etc., a doctor can eliminate alternative causes and reach a conclusion about the most likely cause of a particular patient's condition. It is important to note, however, that differential diagnosis cannot demonstrate general causation, because it assumes, without proving, that all of the potential

- causes considered are capable of causing the condition at issue." Id. at 1157-58 (internal citation omitted).
- "The Ninth Circuit requires general causation opinions to be supported by reliable epidemiological studies or if there are none, a reliable differential diagnosis through which, to a reasonable degree of medical certainty, all other possible causes of the victims' condition can be eliminated, leaving only the toxic substance as the cause." Id. at 1161.
- "Admissible expert testimony need not rule out all alternative causes, but 'where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that it was not the sole cause, that doctor's methodology is unreliable." Id. at 1162 (quoting Heller v. Shaw Indus., Inc., 167 F.3d 146, 156 (3d Cir. 1999)).

Neal-Lomax v. Las Vegas Metro. Police Dep't 574 F. Supp. 2d 1193 (D. Nev. 2008)

Factual Summary

The estate of an arrestee who died after a police officer used a Taser on him brought suit against the manufacturer and the police department, alleging that the Taser was defectively designed to suit its purpose as a non-lethal weapon and lacked sufficient warnings. To support this claim, the plaintiff offered expert testimony from two purported medical experts, Dr. Brett Woodard and Dr. Jared Strote, who opined that the electrical shock from the Taser was a significant factor in causing the decedent's death. The defendant moved to exclude this testimony as unreliable because their methodology consisted solely of reviewing witness statements and the autopsy report and neither individual could point to any peer-reviewed scientific studies that supported their conclusions. The court found that both experts offered opinions that were not based on reliable medical or scientific methodology. As a result, it excluded their testimony.

Key Language

- "The *Daubert* factors may have little application to expert testimony based on personal knowledge or experience. In such circumstances, the trial court should not apply the *Daubert* factors in an unduly restrictive manner." Neal-Lomax, 574 F. Supp. 2d at 1201 (internal citation omitted).
- "An expert's failure to subject his method to peerreview and to develop an opinion outside the litigation does not necessarily render his opinion inadmissible. However, if these guarantees of reliability are absent, the expert must explain his meth-

odology precisely and must 'point to some objective source' supporting his methodology." Id. at 1202 (quoting Lust v. Merrell Dow Pharms., Inc., 89 F.3d 594, 597 (9th Cir. 1996)) (internal citation omitted).

Tech Licensing Corp. v. Gennum Corp. 2004 U.S. Dist. LEXIS (N.D. Cal. Mar. 26, 2004)

Factual Summary

The plaintiff sued the defendant for patent infringement. The defendant filed a motion in limine to exclude testimony of plaintiff's damages expert. The district court conducted a Daubert hearing and excluded the expert's testimony. Expert: Nicholas Feakins.

Key Language

- "However, once Feakins calculates the royalty rate which might have been negotiated between the parties, his analysis and methodology sails into uncharted waters with Federal Circuit law nowhere in sight. Feakins' methodology... is based on purely fictional circumstances." Tech Licensing Corp., 2004 U.S. Dist. LEXIS, at *29.
- "Feakins attempts to create a methodology which supports his theory. However, that theory and methodology used to implement it, fails to comport with applicable Federal Circuit law...." Id. at *30.

DSU Med. Corp. v. JMS Co., Ltd. 296 F. Supp. 2d 1140 (N.D. Cal. 2003)

Factual Summary

The plaintiff sued a competitor for patent infringement. The district court conducted a hearing as to the proffered expert testimony of plaintiff's witness on calculation of damages. The testimony was rejected. Expert: Stephen A. Degnan, Ph.D. (accountant).

Key Language

• "The proffered methodology, requiring inter alia hypothesized terms in hypothesized contracts, is not grounded on established legal principle and is far too remote factually to be within the line drawn for legally compensable patent injuries." DSU Med. Corp., 296 F. Supp. 2d at 1157.

Cloud v. Pfizer, Inc. 198 F. Supp. 2d 1118 (D. Ariz. 2001)

Factual Summary

The plaintiff brought suit against the manufacturer of the antidepressant Zoloft following the suicide of her husband, alleging that use of the drug was linked to

suicide. The defendant sought to exclude the testimony of Dr. Johnstone, the plaintiff's expert witness. The court excluded the testimony. Expert: Dr. Johnstone (board certified psychiatrist in Texas, effects of use of the antidepressant Zoloft).

Key Language

- "[E]ven if we assume that Dr. Johnstone has the expertise to give testimony on issues of epidemiology and psychopharmacology and disregard his deposition testimony denying his expertise in these areas, there is a missing link between the studies upon which he relies and his testimony in this case.... Dr. Johnstone has testified that the articles upon which he relies are only 'strongly suggestive' of the fact that Zoloft causes suicide...." It is "insufficient for [an] expert to speak of possibilities without attempting to quantify those possibilities." *Cloud*, 198 F. Supp. 2d at 1132–33.
- Mere "[c]ompilations of occurrences" have repeatedly "been rejected as reliable scientific evidence supporting an expert opinion that *Daubert* requires." *Id.* at 1133.
- The court found critical concerns with Dr. Johnstone's methodology where he issued his opinion prior to reviewing the autopsy report, hospital records, and the deceased's physician's and therapist's records. The court criticized Dr. Johnstone's failure to explore the role ephedrine and alcohol use might have had in the deceased's death. "The process of assessing alternative and specific causes is one of the hallmark tasks of a physician." *Id.* at 1136.

Colony Holdings, Inc. v. Texaco Ref. & Mktg., Inc. 2001 WL 1398403 (C.D. Cal. Oct. 29, 2001)

Factual Summary

The plaintiffs were notified that there was petroleum-based contamination on three of their properties. The defendants previously operated service stations and pipelines on or near the relevant properties, and the plaintiffs brought nuisance, trespass, and negligence actions against them. The plaintiffs sought to introduce Dr. Linkletter's testimony that the defendant was responsible for the harm to the plaintiff's properties. Finding that Dr. Linkletter's report was conclusory and stated no theory or techniques upon which it was based, the district court granted the defendants' motion to exclude. Expert: Dr. George Linkletter (presumably an expert on environmental engineering—court opinion is not clear, on source of environmental contamination).

Key Language

- "Dr. Linkletter's complete explication of his evaluation process is: 'After a review and analysis of the information provided, I have developed the following opinions.' Because the theory or technique used is unknown, there is no proof that Dr. Linkletter's methods of evaluation have been or even can be tested." Further, there was no evidence of peer review, publication, error rate, or general acceptance of the theory. *Colony Holdings, Inc.*, 2001 WL 1398403, at *3.
- "This report's failure to address other potential causes of the contamination raises questions regarding the thoroughness and objectivity of the process. This is a particularly critical point in this case as there are several possible sources of the contamination." *Id.* at *4.

A&M Records, Inc. v. Napster, Inc. 2000 WL 1170106 (N.D. Cal. Aug. 10, 2000), *aff'd by* 239 F.3d 1004 (9th Cir. 2001)

Factual Summary

Record companies brought an action against an Internet service that allowed users to download various music files. The plaintiffs moved for a preliminary injunction and, in support of their motion, submitted expert reports of several marketing, economics and technology experts. The defendants objected on a number of grounds:

- 1. The defendants objected to the report of Dr. Jay, who surveyed college students to determine the loss of sales suffered by the plaintiffs. The defendants claimed that Dr. Jay's methodology was incorrect because she failed to take into account non-college users of their service. The court disagreed, stating that challenges to methodology of a survey go to the weight the survey should be given, not its admissibility.
- 2. Dr. Fine studied music store trends near college campuses and opined that online music sharing services like that operated by the defendants harmed the plaintiffs by substantially reducing album sales. The defendants claimed that Dr. Fine's methodology was flawed because he failed to take into account a number of explanations for the decline in album sales and that he improperly compared "weighted" statistical numbers with "unweighted" numbers. The court allowed the report for the contention that the plaintiff had suffered "irreparable harm" but noted several concerns, in particular suggesting that it might not allow the report in to show the amount of damages.
- 3. The court found Dr. Teece's report on economic benefits and harms between the parties, because Dr.

Teece's conclusions were based on review of the types of documents any economist would review under the circumstances, such as deposition material and documents produced in the litigation as well as outside studies and media reports.

In turn, the plaintiffs objected to the reports of the defendant's experts as well.

- 1. Dr. Fader used a survey of Internet users to opine that the defendant's music sharing service increased the plaintiff's sales. Particularly, Dr. Fader's opinion was based on a collection of survey results, but when pressed on the methods used to prepare each survey, Dr. Fader could not explain how the results were derived. Although the court did not exclude Dr. Fader's opinion, it stated that it would assign no weight to it.
- 2. Dr. Hall weighed the harm caused by granting versus denying the injunction and opined that the harm would be greater to the defendants. The court refused to exclude the report, noting plaintiff's arguments that Dr. Hall completely ignored several substantial reports and studies contrary to his opinion entirely, but finding any such shortcomings not to be "grave enough."
- 3. Dr. Tygar concluded that it would not be possible to check if all of the material that passed through the defendant's Internet site was copyrighted or not. The plaintiffs objected, arguing that Dr. Tygar's report was not based on "good science" because he did not interview employees or conduct research on the difficulty of copyright verification. The court allowed the report insofar as it discussed the defendants' computer program's capabilities, but excluded the conclusions regarding the ability of people to check for authorization to use copyrights. Experts: Dr. E. Deborah Jay (survey and market research); Michael Fine (market research); Dr. David J. Teece (economics); Dr. Peter S. Fader (marketing); Dr. Robert E. Hall (economics); Dr. J.D. Tygar (computer engineering, security). In this motion for preliminary injunction, Dr. Jay, Mr. Fine, and Dr. Teece were to testify as to irreparable harm. Dr. Fader was to testify to irreparable harm and fair use. Dr. Hall's expertise was on the balance of harms in issuing injunction, and Dr. Tygar's proposed testimony was on the defendant's ability to detect and prevent copyright infringement.

Key Language

• "Defendant misreads Ninth Circuit case law on the impact of *Daubert* on methodological flaws in surveys. The Ninth Circuit has stated that '[c]hallenges to survey methodology go to the weight given the

- survey, not its admissibility." A&M Records, Inc., 2000 WL 1170106, at *3 (citation omitted).
- "The Ninth Circuit has expressed confidence in a jury's ability to decide whether asserted technical deficiencies undermine the probative value of nonscientific expert studies.... The danger of confusion is reduced because the Fine Report does not make claims beyond the limits of its methodology..." Id.

Grant v. Bristol-Myers Squibb 97 F. Supp. 2d 986 (D. Ariz. 2000)

Factual Summary

The plaintiff alleged that silicone breast implants manufactured by the defendant caused her to develop health problems such as chronic fatigue syndrome, breast pain, depression, and dry mouth and eyes. In support of her case, the plaintiff planned to introduce the testimony of experts that silicone breast implants can cause complications and diseases. The court excluded the testimony, and considered the expert's methodology to be unsound because: (1) the experts could not specify their criteria for diagnosis; (2) the experts' theories were incapable of epidemiological testing; and (3) the experts' opinions were based only on clinical experience. Further, the experts' ultimate conclusion was contrary to an "overwhelming" body of evidence. Experts: Dr. Gary Solomon (rheumatology); Dr. Christopher Batich (biomaterials); Dr. Pierre Blais (physical chemistry); Dr. Saul Puszkin (neuroscience, pathology, and immunology); Dr. Douglas Shanklin (pathology); all to testify to a causal link between silicone breast implants and systemic disorders.

Key Language

- "As for the atypical syndrome that is suggested, where experts propose that breast implants cause a disease but cannot specify the criteria for diagnosing the disease, it is incapable of epidemiological testing. This renders the experts' methods insufficiently reliable to help the jury." Grant, 97 F. Supp. 2d at 992.
- "The Court will not allow the jury to speculate based on any experts' opinions based only on clinical experience in the absence of evidence showing consistent, statistically significant association between breast implants and systemic disease." Id.

Brumbaugh v. Sandoz Pharms. Corp. 77 F. Supp. 2d 1153 (D. Mont. 1999)

Factual Summary

The plaintiff, who was twenty-three weeks pregnant, lost her child after being attacked by her boyfriend. Shortly following the incident, the plaintiff was administered the drug Parlodel, manufactured by the defendants, which was used to reduce breast engorgement and associated pain, but, soon thereafter, The plaintiff suffered seizures. Dr. Iffy was called upon to testify that Parlodel caused the plaintiff a chronic seizure condition. Dr. Iffy's conclusion was based on anecdotal case reports and his theory of how the drug affects the body, rather than on epidemiological studies. The Court excluded Dr. Iffy's testimony. Expert: Dr. Iffy (epidemiologist, causation of seizure condition).

Key Language

- "Case reports and [adverse drug events]," such as the "temporal association" between Parlodel and seizures "are compilations of occurrences, and have been rejected as reliable scientific evidence supporting expert opinion so as to meet the requirements set forth in *Daubert*." *Brumbaugh*, 77 F. Supp. 2d at 1156.
- Case reports and adverse drug event reports do not "contain scientific analysis with the safeguards of a controlled experiment. Their most analytical defect is that they don't isolate and investigate the effects of alternative causation agents.... As such, they reflect reported data, not scientific methodology." *Id*.
- Dr. Iffy "admits that [his expert opinion] is 'simply a hypothesis' which has not been tested and may be impossible to test.... Dr. Iffy's unsupported suspicion may be correct but it is not a reliable scientific opinion based on the record before [the Court]." *Id.* at 1157.

Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc. 55 F. Supp. 2d 1024 (N.D. Cal. 1999)

Factual Summary

A university and a research lab brought a lawsuit alleging that the defendants infringed on their patents involving "recombinant DNA technology." In particular, the DNA patented by the plaintiffs exhibited three types of enzymatic activity. The defendants asserted that they were not infringing because two of the three activities were not exhibited in their enzymes. The plaintiffs sought to introduce the expert testimony of Dr. Brown that the defendants' DNA did in fact exhibit one of the activities at issue. The defendants contended that Dr. Brown's opinion was not done in accordance with accepted scientific principles. The court, finding that whether an expert's conclusions concur with those of other experts can be considered when deciding

whether the expert's methodology was sound, excluded Dr. Brown's testimony. Expert: Dr. William E. Brown (DNA expert, whether one party's DNA infringed upon the other's patent).

Key Language

- "According to the plaintiffs, any disagreement between Dr. Brown and the scientific community speaks only to the validity of his conclusions" and not the soundness of his methodology. "The Court disagrees, and finds that the opinions of the scientific community do bear on the admissibility of Dr. Brown's testimony." *Carnegie Mellon Univ.*, 55 F. Supp. 2d at 1032.
- "The fact that Dr. Brown's conclusions are at odds with the scientific findings in two learned treatises and 16 published studies, and are not supported by plaintiffs' other experts, calls Dr. Brown's opinion into question." *Id*.
- "[T]here is no evidence that [Dr. Brown's] method of reinterpretation is practiced by even a minority of scientists in the field." The court than provided a laundry list of Dr. Brown's "depart[ures] from scientific standards," including: "(1) examining only subsets of the controls...; (2) failing to address and exclude alternative explanations...; (4) selectively examining only portions of the data from a number of studies; (5) rejecting studies reporting contrary empirical findings...; (6) relying on data from a notebook based on a contaminated sample that the researchers themselves had examined, tested and rejected;... and (8) relying on sentences from scientific literature taken out of context." *Id.* at 1034–35.

Practice Tip

In *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), the Supreme Court stated that expert testimony may be found unreliable where there is an "analytical gap" between data and conclusions. Thus, as this case illustrates, an expert's conclusions can be a basis of attack on methodology.

United States v. Cordoba

991 F. Supp. 1199 (C.D. Cal. 1998), *aff* d, 194 F.3d 1053 (9th Cir. 1999)

Factual Summary

The defendant was charged with possession of 300 kilograms of cocaine with intent to distribute. The defendant, who admitted to driving the van containing the cocaine, but stated that he did not know of the cocaine's presence, took a polygraph test prior to trial, without the government's knowledge, and

sought to introduce the results of the test at trial. Initially, the court, following circuit precedent providing a per se rule that polygraph evidence should be excluded, barred introduction of defendant's polygraph expert. On appeal, the Ninth Circuit vacated its per se rule, and thus remanded the case. On remand, the district court reassessed the issue and determined again that the polygraph expert's testimony was properly excluded. Expert: Dr. David Raskin (polygraph expert, truthfulness of defendant).

Key Language

- "A scientific theory should be capable of being tested.... [C]ritics do not contest that some settings provide an effective forum to test whether a trained polygrapher can detect deception. In light of this, it appears the polygraph is a testable device." *Cordoba*, 991 F. Supp. at 1202 (internal citation omitted).
- "Hundreds of articles about the polygraph have been published, many in peer-reviewed journals. The polygraph appears to meet the peer review factor of the Daubert analysis." Id. at 1203 (internal footnote omitted).
- The court, after finding that the overall error rate in polygraph tests "is potentially significant," proceeded to find that "[t]here is considerable evidence of a lack of general acceptance in the scientific community for use of polygraph evidence where reliability of the results is critical...." Id. at 1205.
- Finally, the court was critical of polygraphy because "the polygraph industry lacks sufficient *controlling* standards to satisfy Daubert." Id. at 1207.

Butler v. Home Depot, Inc. 984 F. Supp. 1257 (N.D. Cal. 1997)

Factual Summary

Several women alleged they had been denied promotions, transfers, and other advancements based on their gender and sued Home Depot, their employer. In support of their case, the plaintiffs sought to introduce the following witnesses' testimony:

1. Dr. Gentile's testimony was offered to show that the diversity management programs at Home Depot were inadequate. Home Depot alleged that because she had not read all depositions in the matter, cited empirical studies, and had relied extensively on plaintiff's counsel for factual information, Dr. Gentile's methodology was unsound. The Court disagreed, finding that Dr. Gentile's research and knowledge on diversity management alone was suffi-

- cient, and that any challenge to her knowledge of the record should go to weight, not admissibility.
- 2. Home Depot challenged Professor Fiske's conclusions that gender stereotyping played a central role to Home Depot's personnel decisions, and that Home Depot had not done enough to control the effects of the stereotyping, was not methodologically sound because Fiske did not rely on scientific research. Dr. Fiske had reviewed depositions in the case and some non-representative sampling techniques in reaching her conclusions. The Court again determined that, for example, Home Depot's challenges that Fiske "prejudged" the case went to weight and not methodology, and admitted Dr. Fiske's testimony.
- 3. Similarly, the court found that challenges to the methodology employed by Drs. Bielby and Hoffman went to weight and not methodology, as they both drew very narrow conclusions based on a narrow range of information. Experts: Dr. Mary Gentile (organizational diversity program design and implementation); Professor Susan Fiske (social psychology and stereotyping); Dr. William Bielby (sociology and organizational behavior); Dr. Carl Hoffman (statistics).

Key Language

- "Home Depot objects to Professor Fiske's opinion that objective criteria may be better to address the effects of gender-stereotyping than subjective criteria. Home Depot contends that there is no scientific consensus on this subject. Plaintiffs refute this contention. The Court finds that this is a matter best resolved through the adversary procedures of trial." Butler, 984 F. Supp. at 1263 n. 10.
- "To the extent that Home Depot challenges Dr. Fiske's conclusions based on her use of nonrepresentative sampling techniques, Home Depot's argument is misplaced. Professor Fiske does not contend that her examples are representative... [i]nstead, she uses these examples as illustrations of her stereotyping model." Id. at 1263-64.

United States v. Saya 961 F. Supp. 1395 (D. Haw. 1996)

Factual Summary

A criminal defendant sought to introduce expert testimony that the key witness against him may have a limited ability to remember and relate historical events due to years of substance abuse. The district court prohibited the expert from testifying because the expert's knowledge of the facts of the case were based solely on hearsay accounts in an affidavit, the expert could not

cite to a single article suggesting that methamphetamine affects memory, and failed to take into account any of the witness's personal characteristics. Expert: Dr. George Bussey (specialty not given, on effects of narcotics on ability to recall and relate events).

Key Language

- "First, Dr. Bussey's opinion is not supported by scientific methodology and procedures.... Dr. Bussey planned to base his testimony on an affidavit containing hearsay accounts of [the witness's] drug use... [n]ot only is such evidence inherently unreliable; but as Dr. Bussey admitted, it is a methodology unendorsed by any scientific survey, literature or publication." Saya, 961 F. Supp. at 1396.
- "In sum, all the Defendant has put forward is Dr. Bussey's own testimony concerning the reliability of his opinion. However, 'bald assurances of validity' simply do not suffice for *Daubert*." *Id.* at 1397 (citation omitted).

Sanderson v. Int'l Flavors & Fragrances, Inc. 950 F. Supp. 981 (C.D. Cal. 1996)

Factual Summary

The plaintiff sued for personal injuries suffered allegedly resulting from exposure to colognes and perfumes manufactured by the defendant. The plaintiff claimed to suffer from sinus inflammation, brain damaged, dysomia, small airways disease, and multiple chemical sensitivity as a result of acute exposure to formaldehyde in the 1960's–80's and aldehye-containing fragrances more recently. Although the case was thrown out on substantive summary judgment grounds, the court did note that the expert testimony proffered by the plaintiff would not have passed muster. Dr. Nachman Brautbar, internist/nephrologist; Dr. Gunnar Heuser, internist; Dr. Richard Perillo, neurophysicist; Dr. Jack Thrasher, anatomist and cell biologist, all to testify to causation of the plaintiff's various sinus ailments.

Key Language

• "[T]he best way for an expert to provide the requisite 'objective, independent validation' of his methodology is to show that his conclusions are based on his own research, and that his research is legitimately scientific.... Here, none of plaintiff's experts can do this, because none has conducted any research (either before or during this litigation) regarding the health effects of defendants' fragrance products or the aldehydes contained therein." *Sanderson*, 950 F. Supp. at 994.

- "The secondary sources mentioned in plaintiff's opposition do not mention any of plaintiff's claimed injuries or discuss a methodology for determining whether fragrance products or aldehydes have caused particular injuries..." *Id.* at 994–95.
- Dr. Thrasher only attempted to set forth his methodology in the form of a six-part "test" that he administered on the plaintiff. The court responded that it "will not go into detail about whether Thrasher's 'test' is satisfied... Plaintiff has not presented evidence that even one single other scientist follows Thrasher's methodology. As best anyone could tell from the evidence before the court, Thrasher simply made it up." *Id.* at 995.

Diviero v. Uniroyal Goodrich Tire Co. 919 F. Supp. 1353 (D. Ariz. 1996), *aff* d, 114 F.3d 851 (9th Cir. 1997)

Factual Summary

The plaintiffs alleged that the defendant had manufactured a defective tire, causing the plaintiffs to suffer personal injuries in an automobile accident. Mr. Forney had worked with tires for many years and was the president of a tire consulting company, but had never been engaged by the manufacturer of steel belted radial tires, such as the one at issue in the case. Although he testified that he believed the accident was caused by defect due to "an adhesion problem in the skim coat" of the tire, Mr. Forney readily admitted that he knew little of the manufacture or makeup of steel belted tires. The court excluded Mr. Forney's testimony. Expert: Mr. Loren John Forney (engineer in the tire industry, causation of automobile accident).

- "Although the methodology used by Mr. Forney to reach these opinions is not entirely clear it appears to be based upon his experience in examining numerous tires.... His methodology does not include review of independent publications, peer review articles, or independent testing and validation." *Diviero*, 919 F. Supp. at 1359.
- "According to [the tire company's expert] the major flaw in Mr. Forney's methodology was the fact that he did not eliminate other causes for the failure of the tire." *Id.* at 1359–60.
- "[I]n the instant case Mr. Forney's opinions are predictions and unsubstantiated opinions without the incorporation of a valid scientific authority." *Id.* at 1360.

Valentine v. Pioneer Chlor Alkali Co., Inc. 921 F. Supp. 666 (D. Nev. 1996)

Factual Summary

Residents living near a chemical facility alleged that they suffered brain, lung, and nerve damage as a result of chlorine release at the defendant's chemical facility. In support of their case, the plaintiffs sought to call expert doctors to testify as to the effects of exposure to chlorine gas. The court summarily excluded Dr. Heuser's and Dr. Spindell's testimony, finding that both offered conclusory statements and failed to consider other possible causes of the plaintiff's maladies. The court also excluded Dr. Kilburn's testimony because the research forming the basis of the article at the center of his expert opinion did not meet accepted standards. Finally, the court permitted Dr. Hirsch to testify if he could better identify how he reached his conclusions. Experts: Dr. Gunnar Heuser (internist); William Spindell, Ph.D. (expertise unclear, as noted by the court, 921 F. Supp. 2d at 672 n. 7); Dr. Kaye H. Kilburn (internal and preventive medicine); Dr. Alan Hirsch (psychiatry and neurology; whether the plaintiff's injuries were caused by the neuropathological effects of chlorine gas exposure).

Key Language

- "Dr. Spindell admitted that he made no efforts to determine the cause of [the plaintiffs' cognitive and emotional deficits], or to rule out possible etiologies other than chlorine inhalation." Valentine, 921 F. Supp. at 672.
- Dr. Hirsch's "testimony may be admissible if he can 'explain precisely how [he] reached [his] conclusions and point to some objective source... to show that [he has] followed the scientific method..." Id. at 673 (internal citation omitted) (alterations in original).
- "Dr. Kilburn's methodology appears to have ignored a number of important issues. In any epidemiological or toxicological study, the size of the sample population studied is crucial." As Dr. Kilburn studied only seven of the several thousand people exposed to the chlorine gas following the incident at the defendant's facility, "[t]he probability for selection bias is too high to be overlooked. Dr. Kilburn did not select members of the exposed group at random; they are described in his article as 'patients referred to an environmental clinic specializing in neurotoxicology.' This method of selection is unacceptable because the study group has self-selected for disease." Id. at 677.

Frosty v. Textron, Inc. 891 F. Supp. 551 (D. Or. 1995)

Factual Summary

The plaintiff's decedent brought a products liability action against a helicopter manufacturer following a crash. Washington's statute of repose creates a rebuttable presumption that a product's useful life is 12 years, and that at the expiration of that 12 years product liability actions are not actionable. The helicopter at issue in the case was just over 15 years old. To rebut the statute of repose presumption, the plaintiff sought to introduce the testimony of experts that a helicopter has a useful life of well over the 15 years. The court refused to admit the testimony, finding a total lack of explanation of how these experts reached their conclusions. The court proceeded to grant summary judgment to the defendant. Expert: Ramsey Jordan (helicopter pilot); Joseph Barry (mechanic); proffered as experts on the useful life of a helicopter to defeat the presumptions of the applicable statute of repose.

Key Language

• The expert affidavits "fail to explain the methods and procedures used in reaching the conclusion that the useful life of a properly maintained Bell 206 B II helicopter is indefinite. In addition, no external source is cited to validate methodology. The opinions seem to be based on subjective beliefs and unsupported speculation." Frosty, 891 F. Supp. at 554.

Tenth Circuit

Attorney Gen. of Okla. v. Tyson Foods, Inc. 565 F.3d 769 (10th Cir. 2009)

Factual Summary

Oklahoma sought a preliminary injunction against a manufacturer and processor under the Resource Conservation and Recovery Act, based on its distribution of "poultry litter" to farmers for use as fertilizer. Oklahoma alleged this poultry litter contaminated waterways. To support their allegation, Oklahoma offered expert testimony from several experts, including Dr. Valerie Harwood and Dr. Roger Olsen, who used various techniques to attempt to link contamination to the defendant's poultry litter. While the district court admitted the proffered expert testimony for purposes of a hearing on the preliminary injunction, applying Daubert, it concluded that it was unreliable and should be accorded no weight. In an interlocutory appeal, Oklahoma asserted, among other things, that the district court erred in finding Harwood and Olsen's testimony unreliable. The Tenth Circuit disagreed and held that the district court did not abuse its discretion.

Key Language

- "It is an elusive process to divine the difference between a methodology and what constitutes a change from that methodology; therefore, under *Daubert*, we simply hold that 'any step that renders the analysis unreliable renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *Tyson Foods, Inc.*, 565 F.3d at 780 (quoting *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 782 (10th Cir. 1999)).
- "[W]hen experts apply methodologies in novel ways, they may arrive at conclusions that result in 'too great an analytical gap between the data and the opinon proffered to be determined reliable. In other words,... when experts employ established methods in their usual manner, a district court need not take issue under *Daubert*; however, where established methods are employed in new ways, a district court may require further indications of reliability." *Id.* (quoting *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1205 (10th Cir. 2002)).

Neiberger v. Fed Ex Ground Package Sys., Inc. 566 F.3d 1184 (10th Cir. 2009)

Factual Summary

A passenger involved in a motor-vehicle collision with a delivery van filed suit against the van's driver and the driver's employer, a cargo-carrying company. The plaintiff alleged that the collision caused her spine to improperly heal after a prior surgery. The district court permitted the defendants' expert, Dr. Peter Weingarten, to testify. Based on an examination of the plaintiff and a review of imaging studies of her spine, he opined that the plaintiff's spine did not heal because of her smoking, rather than the collision. After the jury returned a defense verdict, the plaintiff appealed, challenging, among other things, the district court's decision to admit Weingarten's testimony. The Tenth Circuit affirmed.

Key Language

"Dr. Weingarten's methodology was one generally accepted in the medical community and by the courts. He simply considered the possible recognized causes and eliminated those contradicted by the evidence before him. To use somewhat technical language, he began with scientific support for 'general causation'—that smoking can cause nonunions—

and concluded that smoking was likely the 'specific' cause in this instance after he had eliminated the possibility that the accident had been the cause." *Neiberger*, 566 F.3d at 1190–91.

Mariposa Farms, LLC v. Westfalia-Surge, Inc. 211 F. App'x 760 (10th Cir. 2007)

Factual Summary

A farm sued the manufacturer of cow-milking equipment, alleging that its equipment malfunctioned and resulted in disease spreading through its herd of cows. One of the experts offered by the plaintiff to support its claims was Dr. Robert Corbett. Corbett testified that, based on his experience, the milking machine malfunction caused the breakout. On appeal, the defendants alleged that the district court erred in permitting this testimony, because Corbett's methods were unreliable and not based on generally accepted standards promulgated by the American Society of Agricultural Engineers. The Tenth Circuit disagreed and found that Dr. Corbett's testimony was based on a scientifically valid methodology and had been properly admitted.

Key Language

- "In this case, Dr. Corbett's use of a process known as reasoning to the best inference to arrive at his conclusions was sufficiently reliable under *Daubert* and *Kumho*, and the district court did not abuse its discretion in admitting his testimony." *Mariposa Farms L.L.C.*, 211 F. App'x at 763.
- "...Dr. Corbett's testimony provided the jury with sufficient evidence to find that Westfalia was negligent and breached its warranties. He studied the milking machine, Mariposa's management, and through the logic of best inference, reasonably deduced that the milking machine was defective because he had never seen a mastitis outbreak spread so rapidly where defective equipment was not the culprit. This methodology was reliable and provides a sufficient basis to conclude that the milking machine was defective." *Id.* at 764.

United States v. Rodriguez-Felix 450 F.3d 1117 (10th Cir. 2006)

Factual Summary

The defendant was convicted of distributing cocaine. At trial, he offered expert testimony from Dr. Steven E. Clark on the general reliability of eyewitness testimony. The district court excluded Dr. Clark's testimony as unreliable. On appeal, the defendant challenged this

exclusion. The Tenth Circuit found that the district court did not abuse its discretion and affirmed.

Key Language

• "The requirements of *Daubert* are not satisfied by casual mention of a few scientific studies, which fail to demonstrate that an expert's conclusions are grounded in established research, recognized in the scientific community, or otherwise accepted as scientific knowledge." *Rodriguez-Felix*, 450 F.3d at 1126.

Miller v. Pfizer, Inc. 356 F.3d 1326 (10th Cir. 2004)

Factual Summary

The parents of a 13-year-old boy sued the manufacturer of Zoloft when their son committed suicide after being on the drug for one week. The district court granted summary judgment for the defendants after excluding plaintiff's expert testimony on the grounds that the methodology employed was scientifically unreliable. The plaintiffs appealed the decision, saying that the district court abused its discussion as a gatekeeper when it refused to allow the plaintiff's expert to introduce new supporting evidence in response to concerns raised by two independent experts tasked with evaluating his methodology. The Tenth Circuit upheld the decisions of the lower court. Experts: David Healy, M.D. (neuropsychopharmacology); John Concato, M.D., M.S., M.P.H. (independent evaluating expert); John M. Davis, M.D. (independent evaluating expert).

Key Language

- "The court also decided that placing substantial emphasis on a few challenge-dechallenge-rechallenge studies and case reports is not a generally accepted methodology." *Miller*, 356 F.3d at 1330.
- "Concerned, however, about 'Dr. Healy's reliance on pre-selected evidence from interested parties, to the exclusion of reliable evidence that Matthew engaged in suicidal thoughts and behavior before he first used Zoloft,' the court had 'asked its independent experts whether selective reliance was consistent with generally accepted methodology on the issue.' The independent experts informed the court that such selective reliance was not a generally accepted methodology." *Id.* at 1331 (internal citation omitted).

Truck Ins. Exch. v. MagneTek, Inc. 360 F.3d 1206 (10th Cir. 2004)

Factual Summary

The plaintiff in a products liability case alleged that a

fluorescent light ballast manufactured by the defendant caused a fire. The district court found that plaintiff's experts' conclusions about the cause of the fire were not based on a sufficiently reliable scientific theory, and granted summary judgment for the defendant. The Tenth Circuit affirmed. Expert: Dr. Romig (physicist, fire causation expert).

Key Language

• "The district court was correct in finding that three scholarly articles "cast doubt on the general scientific acceptance, the methodology, and the adequacy of the experimentation underlying pyrolysis at this time. It was therefore within the district court's discretion to reject the theory as insufficiently reliable to form the basis of expert testimony." Truck Ins. Exch., 360 F.3d at 1212.

Dodge v. Cotter Corp.

328 F.3d 1212 (10th Cir. 2003), cert. denied, 124 S. Ct. 533 (2003)

Factual Summary

A number of plaintiffs' groups sued, alleging property damage as a result of contamination of water caused by the defendant's uranium mill. The Tenth Circuit concluded that the district court had failed to perform its gatekeeper function, because a *Daubert* hearing was necessary prior to admission of plaintiffs' disputed expert testimony. As a result, it reversed and remanded. Experts: Glen Miller (geologist), Mallin Dollinger (M.D. and oncologist), Dr. Martin Smith (toxicologist).

Key Language

- "Faced with an exceedingly difficult, complex case and obvious docket pressures, the court did not make adequate findings on the record to assure that the expert testimony offered was both relevant and reliable, and that the particular opinions were based on valid reasoning and reliable methodology." *Dodge*, 328 F.3d at 1226.
- "Although the court apparently alludes to Dr. Smith's methodology, it made no specific findings and really did nothing more than note an indication that his methodology was the same as that used outside the context of litigation." *Id.* at 1229.

Goebel v. Denver & Rio Grande W. R.R. Co. 346 F.3d 987 (10th Cir. 2003)

Factual Summary

An employee alleged he was injured in a tunnel mishap. The Tenth Circuit rejected the employer's argu-

ment that the district court abused its discretion by admitting expert testimony as to causation. Expert: Dr. Daniel Teitelbaum.

Key Language

- "Under *Daubert*, any step that renders the analysis unreliable... renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *Goebel*, 346 F.3d at 993.
- "Dr Teitelbaum's methodology is scientifically sound and... his opinion reasonably flows from the data upon which he purportedly relies." *Id.* at 994.

Hollander v. Sandoz Pharms. Corp. 289 F.3d 1193 (10th Cir. 2002)

Factual Summary

The plaintiffs filed a products liability action alleging that Parlodel, a drug manufactured by the defendant and distributed by a hospital caused Ms. Hollander to suffer an intracerebral hemorrhage shortly after she gave birth. The district court ruled that the plaintiffs' expert testimony regarding the causal connection between Parlodel and intracerebral hemorrhages lacked the necessary reliability; as a result, Hollanders' expert testimony was inadmissible. The Tenth Circuit affirmed in part and reversed in part. Experts: Dr. Kenneth Kulig (physician who is board-certified in toxicology and emergency medicine); Dr. Leslie Iffy (professor in the Department of Obstetrics and Gynecology of the Department of Medicine of New Jersey); Dr. Pedro A. Jose (professor of Pediatrics, Physiology and Biophysics at Georgetown University and an expert on the role of dopamine and dopaminergic drugs on the development of hypertension).

Key Language

- "Under *Daubert*'s reliability prong for determining admissibility of expert testimony, an inference or assertion must be derived by the scientific method and must be supported by appropriate validation." *Hollander*, 289 F.3d at 1193.
- "Dr. Kulig could only list possible mechanisms for Parlodel causing hypertension, Dr. Jose could not cite any studies or tests that proved his hypothesis, and Dr. Iffy classified her opinion as being a hypothesis, which is not held by a medical degree of certainty." *Id.* at 1202.

Sallahdin v. Gibson 275 F.3d 1211 (10th Cir. 2002)

Factual Summary

A defendant was convicted of murder in the state court. In a petition for habeas corpus, he alleged that the state trial court erred in barring testimony from the petitioner's physician regarding "Steroid Rage Syndrome" (SRS), and that counsel rendered ineffective assistance by not presenting the expert's more general testimony on the effects of steroids on petitioner's state of mind. The district court denied the petition. The Tenth Circuit reversed, agreeing with the district court's conclusions, but concluded the dispositive fact was that the state trial court barred only testimony relating specifically to SRS, leaving the admissibility of other steroid evidence open. As for penalty phase, however, physician's testimony on the effects of steroid usage was relevant and reflected emerging scientific consensus (although physician conceded that "Steroid Rage Syndrome" was not specifically recognized). Testimony was therefore admissible under Daubert. Expert: Dr. Harrison Pope (psychiatrist and steroid expert).

Key Language

• "Applying the above-outlined standards to Dr. Pope's proposed testimony, we conclude that the proposed testimony was admissible during the sentencing phase of the trial. In short, we are persuaded that Dr. Pope's conclusions regarding the effects of anabolic steroids were based upon scientific knowledge for purposes of *Daubert v. Merrell Dow Pharms., Inc.*, and thus were sufficiently reliable." *Sallahdin*, 275 F.3d at 1238.

Alfred v. Caterpillar

262 F.3d 1083 (10th Cir. 2001)

Factual Summary

While working with the naval construction battalion, a naval service member was injured by an asphalt paver. She brought a products liability action against the manufacturer of the paver. She alleged that the paver's design was defective and that the defect caused her injury. The district court granted the defendant's motions to strike the plaintiff's expert testimony, and for judgment as a matter of law. The plaintiffs appealed. The Tenth Circuit affirmed. Expert: William P. Munsell (mechanical engineer).

- "Mr. Munsell gave an opinion that was very limited and it was backed by very little work and very little expertise." *Alfred*, 262 F.3d at 1086.
- The district courts must assess the "reasoning and methodology underlying the expert's opinion, and de-

termine whether it is scientifically valid and applicable to a particular set of facts." Id. at 1083.

United States v. McPhilomy

270 F.3d 1302 (10th Cir. 2001), cert. denied, 122 S. Ct. 1384 (2002)

Factual Summary

The defendants removed several tons of stone from a government community pit without proper permits and were charged with aiding and abetting each other in the theft of government property. The defendants objected to testimony from the government's geologist regarding the quality, quantity, and value of the stone. The Tenth Circuit affirmed the district court's decision to admit this testimony. The geologist inspected stone, had considerable training and experience, and used same methods he utilized when performing work for Bureau of Land Management (BLM). More extensive and costly tests might have been preferable, but the geologist's work was sufficiently reliable to support his opinion on quality of stone. He also employed common method for estimating tonnage—i.e., he estimated volume of stone and calculated weight based on data provided for that purpose in BLM publication. Further, the geologist could properly estimate retail value by inquiring at other stone yards about retail prices of comparable stone. Expert: Michael Ford (BLM employee).

Key Language

- "Ford explained that he had viewed the stone and that he had employed a common method of estimating the tonnage, by estimating the stone's physical volume and then calculating its weight based on data provided for that purpose in a standard BLM publication. Based on this testimony at the Daubert hearing, the district court did not abuse its discretion in finding Ford's testimony as to the quantity of the stone sufficiently relevant and reliable to be admissible." McPhilomy, 270 F.3d at 1313.
- "Given his considerable experience and expertise, Ford's use of the same methodology that he uses as a certified mineral examiner for the BLM, and his firsthand observations, it was not manifestly erroneous for the district court to admit his expert testimony as to the quality of the stone." Id.

Black v. M&W Gear Co. 269 F.3d 1220 (10th Cir. 2001)

Factual Summary

A widow's husband was killed when his lawn mower

tipped over. The widow brought a products liability action against the mower's manufacturer. The plaintiff's theory was that the mower was defective because it did not have any rollover protective structure (ROPS). The manufacturer offered an engineering expert to testify that ROPS would not have prevented fatality. The district court excluded this testimony because the expert made no tests or calculations. The Tenth Circuit affirmed. Expert: Dr. Clary (agricultural engineering and Ph.D. in engineering).

Key Language

• "The district court properly noted that Dr. Clary had not conducted any tests or calculations to support his opinion. Defendants note that Dr. Clary had the requisite background to be able to testify that a ROPS would not have prevented the fatal injuries to Black. The district court did not, however, exclude the testimony because of Dr. Clary's lack of qualifications. Instead, it excluded the evidence because Dr. Clary had not based his conclusion on the results of tests or calculations specific to Black's accident." Black, 269 F.3d at 1238.

Smith v. Ingersoll-Rand Co. 214 F.3d 1235 (10th Cir. 2000)

Factual Summary

In a product liability action against a machine manufacturer, an injured worker offered testimony on design defects from a human factors engineer and from a safety consultant, as well as non-quantitative testimony on hedonic damages from a forensic economist. The manufacturer appealed following a jury verdict of \$27 million in compensatory and punitive damages. The Tenth Circuit affirmed the admissibility of the plaintiff's expert testimony. As to the plaintiff's forensic economist, the defendant succeeded in excluding the economist's testimony on the value of the plaintiff's hedonic damages, and so he testified only to the commonsense qualitative proposition that the value of life is not measured exclusively by individual's earning power. The Tenth Circuit concluded that the district court soundly exercised its discretion in permitting this component of the economist's testimony. Expert: Stan Smith (forensic economist).

Key Language

 "Ingersoll-Rand's claim necessitates differentiating hedonic damages as a concept from the methodology generally used in their computation. The concept of hedonic damages is premised on what we take to be the rather noncontroversial assumption that the

- value of an individual's life exceeds the sum of that individual's economic productivity." *Smith*, 214 F.3d at 1243.
- "Attempts to quantify the value of human life have met considerable criticism in the literature of economics as well as in the federal court system. Troubled by the disparity of results reached in published value-of-life studies and skeptical of their underlying methodology, the federal courts which have considered expert testimony on hedonic damages in the wake of *Daubert* have unanimously held quantifications of such damages inadmissible." *Id.* at 1245.

Goebel v. Denver & Rio Grande W. R.R. Co. 215 F.3d 1083 (10th Cir. 2000)

Factual Summary

A railroad conductor alleged neurological symptoms resulted from prolonged inhalation of diesel fumes while trapped in tunnel. The district court admitted testimony from the conductor's toxicologist, Dr. Daniel Teitelbaum, to this effect. On appeal, the railroad argued that the district court erred in admitting this testimony, which purported to establish a causal link between the plaintiff's cognitive brain damage and exposure to diesel exhaust at high altitude. The Tenth Circuit reversed and remanded for a new trial, concluding that nothing in record indicated that the district court conducted any *Daubert* inquiry at all. Expert: Dr. Daniel T. Teitelbaum (medical doctor specializing in toxicology).

Key Language

• The "gatekeeper function requires the judge to assess the reasoning and methodology underlying the expert's opinion, and determine whether it is scientifically valid and applicable to a particular set of facts." *Goebel*, 215 F.3d at 1083. In evaluating the admissibility of the proffered expert testimony the court was, "unable to discern whether the court was referring to the professional credentials of the witness as opposed to assessing the reasoning and methodology relied upon by the witness. It is axiomatic that an expert, no matter how good his credentials, is not permitted to speculate." *Id.* at 1088.

Hynes v. Energy West, Inc. 211 F.3d 1193 (10th Cir. 2000)

Factual Summary

Apartment residents who were injured during a natural gas explosion brought suit against the natural gas supplier, contending that a dangerous condition went undetected because the gas company improperly odorized its natural gas. To support their claims, the plaintiffs' chemist testified that gas lost its odor by interaction with alkalines and/or iron oxides in the soil between pipeline leak and building basement, and that use of odorant thiophene would have prevented or mitigated odor loss. The district court admitted this testimony. The Tenth Circuit affirmed. Specifically, the Tenth Circuit rejected the defendants argument that the chemist's testimony satisfied none of the Daubert factors, stating that those factors were not essential, and, given the chemist's substantial education and industry experience, he was able to articulate a scientific process through which gas odor loss would occur. Expert: Duane Kniebes (chemist, gas odorization).

Key Language

- "The subject of an expert's testimony must be 'scientific... knowledge.' The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation.... In order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Hynes*, 211 F.3d at 1203–04.
- In admitting the testimony of the plaintiff's expert the circuit stated that, "the trial court did not abuse its discretion when it chose to admit expert testimony of Duane Kniebes concerning industry practice and the neutralization and oxidation theories. Kniebes had extensive scientific credentials and he was able to articulate a scientific process by which neutralization and oxidation occurs." *Id.* at 1205.

United States v. Nichols 169 F.3d 1255 (10th Cir. 1999)

Factual Summary

The defendant, a co-conspirator in the planning and subsequent bombing of the Alfred P. Murrah Federal Building in Oklahoma City, was convicted of conspiring to use a weapon of mass destruction and eight counts of involuntary manslaughter. On appeal, the defendant submitted eleven grounds for reversal, including that the district court erred before and during trial when it admitted the expert testimony

of Linda Jones and excluded the expert testimony of Dr. Fredric Whitehurst. The Tenth Circuit affirmed. Experts: Linda Jones (forensic explosive); Dr. Fredric Whitehurst (FBI agent).

Key Language

• "Ms. Jones' expert testimony enhanced the prosecution's case that Mr. Nichols conspired to use a weapon of mass destruction because she testified the bomb was consistent with the materials the prosecution proved to be within the possession of Mr. Nichols." Her scientific theory and testing methodologies were relevant. Nichols, 169 F.3d at 1266.

Duffee & Thornton v. Murray Ohio Mfg. Co. 91 F.3d 1410 (10th Cir. 1996)

Factual Summary

Following a juvenile's collision with a car, the juvenile and his parents brought a products liability action against the bicycle manufacturer, bicycle seller, and coaster brake manufacturer, alleging warning, design and manufacturing defects under negligence, strict liability, and warranty theories. The defendants moved for summary judgment. The district court granted summary judgment to seller and bicycle manufacturer, and granted summary judgment to brake manufacturer in subsequent order after excluding the plaintiffs' expert's scientific testimony. The Tenth Circuit affirmed.

Key Language

- "When a district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment, we will give them a 'hard look' (more stringent review) to determine if a district court has abused its discretion in excluding evidence as unreliable." Duffee, 91 F.3d at 1411.
- "Daubert requires the district judges to act as gatekeepers to ensure that scientific evidence is both relevant and reliable. This entails two inquiries: whether the reasoning and methodology underlying the testimony is scientifically valid, and whether the reasoning and methodology can properly be applied to the facts." Id.

United States v. Reed 40 F.3d 1069 (10th Cir. 1994)

Factual Summary

The defendants were convicted of various offenses resulting from attempted armed robbery of a credit union. The defendants appealed, contending that the trial court erred by admitting DNA evidence at trial. They argued that the court failed to adequately investigate whether the government followed protocol, and therefore that the government failed to establish reliability of the DNA testing in this case. The Tenth Circuit affirmed. Expert: Agent Lynch (specialized training in DNA profiling).

Key Language

- "Parties stipulation that deoxyribonucleic acid testing is a generally accepted scientific technique, satisfied the first prong of the current test under Daubert, that the reasoning or methodology underlying testimony be scientifically valid." Reed, 40 F.3d at 1069.
- "District court's acceptance of expert's qualification will be disturbed only for clear abuse of discretion." Id.

Graves v. Mazda Motor Corp. 675 F. Supp. 2d 1082 (W.D. Okla. 2009)

Factual Summary

The driver of an automobile and her husband brought a products liability claim against the vehicle's manufacturer, alleging that a defective gear shifter caused the crash. To support their claim, the plaintiffs offered expert testimony from Stephen Syson. Based on an inspection of the subject vehicle, a review of video of the defendant's experts evaluating the subject vehicle, and a review of the plaintiff's deposition, he opined that the gear shifter was defectively designed. The defendant moved to exclude this testimony, arguing that his opinions were unreliable. The district court agreed and held that, inter alia, Syson's defect opinions rested on a flawed and unreliable methodology. As a result, the court excluded his testimony in its entirety.

- "Although Mr. Syson's conclusions—including his central conclusion that the Mazda6 shifter is defective because it is different—are purportedly based on the application of engineering principles, his application of those principles to the shifter on the Mazda6 is not grounded in any objective data or specifically applicable engineering standards.... [H]e did no testing to quantify—or even to confirm the existence of—any exceptional propensity of the gated shifter on the Mazda6 to cause driver confusion about the actual position of the shift lever." Graves, 675 F. Supp. 2d at 1102.
- · "Although human factors engineering is a legitimate discipline, in a forensic setting, the application

of human factors principles can be highly subjective and thus conveniently malleable. Human factors testimony which is proffered without a showing of objective support (testing or, at least, independent support in relevant literature) invites close scrutiny to determine whether the expert's work is an exercise in facile advocacy (e.g., the 'ipse dixit of the expert')." *Id.* at 1103 (internal footnote omitted).

Rimbert v. Eli Lilly & Co. 2009 WL 2208570 (D. N.M. July 21, 2009)

Factual Summary

The estate of a patient who murdered his wife and committed suicide brought an action against the manufacturer of an antidepressant, arguing that the drug caused the decedent's actions. The plaintiffs offered expert testimony from Dr. Grace Jackson on general and specific causation and on the manufacturer's alleged failure to warn or properly test the drug. The defendant moved to exclude this testimony, arguing that Dr. Jackson was not qualified to express this opinion because she based her opinion on flawed methodology. The court agreed and granted the motion to exclude.

Key Language

- "An untested hypothesis does not provide a scientifically reliable basis for an opinion on causation." *Rimbert*, 2009 WL 2208570, at *12.
- "Courts have excluded experts' opinions when the experts depart from their own established standards or the standards followed in their field." *Id.* at *14.
- "By relying on articles that only present hypotheses, and extrapolating from those articles to state hypotheses of her own, which she then uses to form the basis for her conclusion, Dr. Jackson has not moved beyond the first step in the scientific method upon which she purportedly relied. Untested hypotheses do not form the basis for admissible scientific opinions." *Id.* at *15.
- "The failure of her methodology is somewhat amplified by the fact that, in addition to failing the *Daubert* factors of general acceptance in the scientific community and following scientific standards (*i.e.*, failure to follow the Hill standard and the scientific method, as discussed earlier), it falls short on another *Daubert* factor as well. Dr. Jackson admits that she never attempted to publish the methodology she employed to generate her opinion in any peer reviewed journal, nor did she seek to have her methodology peer-reviewed by any other means such as presentation at a scientific meeting. Instead, her

- opinion and the methodology enabling it were created strictly for this litigation." *Id.* at *16 (internal citation omitted).
- "The differential diagnosis method requires that potential causes for an outcome (in this case, a homicide and suicide) be ruled in as possibilities using valid scientific evidence, and then, using a process of elimination, be ruled out, if possible, using valid scientific evidence. Differential diagnosis, if properly applied, is a valid technique for determining specific causation." *Id.* at *18 (internal citation omitted).
- "A methodology that inexplicably ignores material facts and relies only on selective evidence does not lead to a reliable opinion." *Id.* at *20.

Pekarek v. Sunbeam Prods., Inc. 672 F. Supp. 2d 1161 (D. Kan. 2008)

Factual Summary

Homeowners brought a products liability claim against the manufacturer of an electric blanket, alleging that a defect in the blanket caused a fire that extensively damaged their home. To support this claim, the plaintiffs offered testimony from Chris Komarek, the fire chief who responded to the fire, as a purported fire investigation expert. Komarek opined that the fire started because the blanket malfunctioned. He lacked substantial knowledge of NFPA 921 and did not attempt to follow it during the course of his investigation. The defendant challenged this testimony, arguing, in part, that it was not based on a scientifically reliable methodology. The court concluded that Komarek's opinion as to the origin of the fire was reliable, even though it did not follow NFPA 921, but that his opinion that the blanket caused the fire was based on an unreliable methodology.

Key Language

- "[M]any courts have described the methodology in NFPA 921 as 'a peer reviewed and generally accepted standard in the fire investigation community.' On the other hand, courts have said a failure to strictly adhere to NFPA 921 does not render an investigation per se unreliable." *Pekarek*, 672 F. Supp. 2d at 1175 (quoting *Workman v. AB Electrolux Corp.*, No. 03-4195-JAR, 2005 WL 1896246, at *10 (D. Kan. Aug. 8, 2005)).
- "The mere fact [the expert] did not cite or use NFPA 921 as his guide does not necessarily mean he failed to use a reliable method." *Id*.
- "The failure to fully consider the condition of the primary item suspected to be the fire's source cannot

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be considered a reliable method of fire investigation." *Id.* at 1176.

Windham v. Circuit City Stores, Inc. 420 F. Supp. 2d 1206 (D. Kan. 2006)

Factual Summary

Homeowners brought an action against Circuit City, alleging that it negligently installed a range cordset that caused a fire. The plaintiffs offered testimony from James Martin, an electrical engineer, who concluded that the fire was caused either because the cordset was defective or had been damaged during installation. The defendant argued, inter alia, that Martin did not use the scientific method to properly eliminate other sources of the fire, did not conduct any tests, and, therefore, that his opinions were unreliable. The court disagreed and found Martin's opinions to be sufficiently relevant and reliable.

Key Language

- "An inference to the best explanation for the cause of the accident must eliminate other possible sources as highly improbable, and must demonstrate that the cause identified is highly probable.' However, an expert need not definitively exclude every possible alternative to testify on causation." Windham, 420 F. Supp. 2d at 1212 (quoting Bitler v. A.O. Smith Corp., 400 F.3d 1227, 1238 (10th Cir. 2004)).
- "Failure to adequately explain this one alternative cause of fire does not render Martin's analysis completely unreliable." *Id*.
- "Defendant next argues that Martin's conclusions are unreliable because he did not conduct any tests. Testing is not the determinative factor." *Id.*

Werede v. Allright Holdings, Inc. 2005 WL 2124553 (D. Colo. 2005)

Factual Summary

The plaintiff filed a race and national origin discrimination suit against his employer based on a "Preliminary Report on the Impact of Race and National Origin on Workforce Utilization and Compensation at Allright Parking 1992–2000" by Dr. Andrew Bardwell. The defendants filed a motion to exclude the expert testimony of Dr. Bardwell as failing to meet the *Daubert* standard of admissibility due to unreliable methodology and submitted the work of its own expert, Dr. George F. Rhodes, on the subject. The court held that the opinions of Dr. Bardwell were not admissible. Experts: Dr. Andrew Bardwell & Dr. George F. Rhodes.

Key Language

- "The Tenth Circuit has not so sharply bifurcated the issues between methodology and its application although it has concluded that improper application may render expert opinion evidence irrelevant." Werede, 2005 WL 2124553, at *2.
- "Although pre-*Daubert*, the case [*Bazemore*, 478 U.S. at 400] remains authority for the basic proposition that regression analyses are acceptable even though not all measurable variables were included." *Id.* at *3.
- "With this background, the issue distills down to whether a recognized methodology using so few variables was still properly applied so as to serve as evidence from which discrimination may be inferred. Given Tenth Circuit authority on the use of statistical evidence in discrimination cases, I conclude it cannot." *Id.* at *4.
- "Focusing on the issue of reliability of the stated opinion of Dr. Bardwell in context of this Tenth Circuit authority requiring the elimination of non-discriminatory reasons for numerical disparities, I find the plaintiff's evidence to be lacking. The non-discriminatory variables should have been included in the plaintiff's analysis and were not. As defendant's expert concludes, their absence renders any inference from the regression analysis unreliable. The failure of the defendant to produce evidence necessary for a proper regression analysis, for whatever reason, does not make unreliable evidence admissible either outright or subject to defendant disproving the unreliable inference with more evidence." *Id.* at *5.

United States v. Cline 188 F. Supp. 2d 1287 (D. Kan. 2002)

Factual Summary

The defendants were charged with various drug trafficking offenses and moved to exclude certain evidence, including expert testimony or expert reports that the "latent print obtained from the government's exhibit N-46 matches one of Cline's rolled fingerprints from a fingerprint card." The defendants argued that such expert testimony failed the standard articulated in *Daubert*. The district court granted the motion in part, and denied in part.

Key Language

 "When a trial court finds the theory reliable that fingerprints are unique and permanent and ascertains that there is an established and accepted methodology for matching fingerprints, its gatekeeping role has been served and now the jury must determine whether the expert witness has properly applied this theory and methodology to the case." *Cline*, 188 F. Supp. 2d at 1296.

Eleventh Circuit

Kilpatrick v. Breg, Inc. 613 F.3d 1329 (11th Cir. 2010)

Factual Summary

A patient who was diagnosed with chondrolysis, a breakdown of cartilage in his shoulder, brought an action against a pain pump manufacturer, alleging that his use of the pump following arthroscopic shoulder surgery caused his condition. To support this claim, the plaintiff offered testimony from Dr. Gary Poehling, who opined that the pain pump caused the chondrolysis. The defendant moved to exclude this testimony, arguing that his methodology was unreliable because he made unjustifiable extrapolations from the existing literature, did not explain the background risk, and that his specific causation conclusion was premised upon nothing more than a temporal relationship. The district court agreed and granted the defendant's motion. The Eleventh Circuit affirmed.

Key Language

• "Kilpatrick next contends that because the methods Dr. Poehling used to reach his conclusions (reviewing medical literature and the 'differential diagnosis' methodology) were not new or novel, the district court should have refrained from assessing the reliability of these methods and should have focused solely on whether Dr. Poehling was qualified to testify as an expert—testimony that would have been helpful to the jury. Such an approach goes against the law of this Circuit, which has reversed trial courts who abdicate their gatekeeper role and refuse to assess reliability. To be sure, there are instances in which a district court may determine the reliability prong under *Daubert* based primarily upon an expert's experience and general knowledge in the field; but at all times the district court must still determine the reliability of the opinion, not merely the qualifications of the expert who offers it.... [I]t was entirely proper—indeed necessary—for the district court to focus on the reliability of these sources and methods. To hold otherwise would encourage trial courts to simply rubber stamp the opinions of expert witnesses once they are determined to be an expert." 619 F.3d at 1137.

- "[T]he Hansen study was merely a compilation of case reports without any statistical context. Such studies 'lack control[] and thus do not provide as much information as controlled epidemiological studies do... Causal attribution based on case studies must be regarded with caution.' Faced with a study that failed to explain why 40 percent of patients treated with intra-articular pain pumps did not develop chondrolysis, the lack of any statistical analysis discussing the relative importance of this study, the failure to account for other causes of chondrolysis, and the omission of any conclusion on general causation, the district court did not abuse its discretion in finding that the Hansen study was not a source upon which Dr. Poehling could reasonably rely under [Federal Rule of Evidence] 702. Kilpatrick's focus on the authors' description of an 'association' between pain pumps and glenohumeral chondrolysis is unavailing." Id. at 1338 (quoting McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1253 (11th Cir. 2005)) (alterations in original) (internal citations omitted).
- "[B]y its own words, the Gomoll study at most suggests a connection between the use of intra-articular pain pumps, bupivacaine, and chondrolysis in rabbit cartilage. This does not equate to a conclusion of direct causation (or a connection of any degree) between the use of such pain pumps and chondrolysis in humans.... Dr. Poehling also could not explain the possible differences in dose-response relationship between humans and rabbits. As the district court correctly noted, a dose-response relationship is 'the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect.' The lack of any data or any explanation by Dr. Poehling on this point puts the methodology of both the Gomoll study, and Dr. Poehling's general causation opinions in question." Id. at 1339 (quoting McClain, 401 F.3d at 1242) (internal citations and footnote omitted).
- "The court does not intend to suggest that in order to survive *Daubert* review, a methodology based on a review of existing literature on the subject must rely on articles that draw a direct, concrete, and absolute causal connection. However, in this case, given the paucity of reliable evidence and the speculative nature of the articles Dr. Poehling relied upon, the court cannot disagree to the point of finding an abuse of discretion in the district court's conclusion that Dr. Poehling's methodology on general causation was not reliable for purposes of Rule 702." *Id.* at 1341.
- "Kilpatrick is correct that differential diagnosis itself has been recognized as a valid and reliable method-

ology. But that is not the issue about which the district court found fault. Rather, the district court found that Dr. Poehling's application of this methodology was flawed. In order to correctly apply this methodology, Dr. Poehling must have compiled a comprehensive list of potential causes of Kilpatrick's injury and must have explained why potential alternative causes were ruled out. However, Dr. Poehling only ruled out two causes—thermal energy and gentian violet contrast dye. He clearly testified that he could not explain why potentially unknown, or idiopathic alternative causes were not ruled out. Dr. Poehling also admitted that neither he nor anyone else in the medical community 'understands the physiological process by which [chondrolysis] develops and what factors cause the process to occur.' Thus, the key foundation for applying differential diagnosis was missing, and based on these deficiencies, the district court found that Dr. Poehling failed to apply the differential diagnosis methodology reliably. The district court did not abuse its discretion in so concluding." *Id.* at 1343.

- "Kilpatrick cannot overcome the fact that Dr. Poehling's specific causation testimony is rooted in a temporal relationship.... This is a classic 'post hoc ergo propter hoc' fallacy which 'assumes causation from temporal sequence. It literally means after that, because of this.... It is called a fallacy because it makes an assumption based on the false inference that a temporal relationship proves a causal relationship.' Dr. Poehling made clear that he reached his conclusions with respect to Kilpatrick's injuries merely by looking at Kilpatrick's shoulder before and after the use of Breg's pain pump. The district court did not abuse its discretion in finding Dr. Poehling's methodology to establish specific causation unreliable under Daubert." Id. (quoting McClain, 401 F.3d at 1243).
- "The law of this Circuit is clear that the district courts are given broad discretion with wide latitude in conducting a Daubert analysis and concluding that methodologies based on speculative literature and temporal proximity analysis such as the type relied upon by Dr. Poehling are not sufficient to pass Daubert review." Id.

Hendrix v. Evenflo Co. 609 F.3d 1183 (11th Cir. 2010)

Factual Summary

The parent of an infant injured during an automobile crash brought an action against the manufacturer of the child's car seat, alleging that the seat was defectively designed and did not protect the child during a minor collision. Although there were no immediate signs of permanent brain injuries, approximately three years after the crash, the child began to exhibit developmental problems. The plaintiff offered testimony from medical experts who opined that these problems were caused by the crash. These experts stated that they reached their conclusions by conducting a differential diagnosis, or, more specifically, a differential etiology. The district court granted the manufacturer's motion to exclude this testimony, concluding that the methodology used by the plaintiff's experts was not sufficiently reliable. The Eleventh Circuit affirmed.

- "[T]he reliability of the method must be judged by considering the reasonableness of applying the differential etiology approach to the facts of this case and the validity of the experts' particular method of analyzing the data and drawing conclusions therefrom." Hendrix, 609 F.3d at 1195.
- "A reliable differential etiology analysis is performed in two steps. First, the expert must compile a 'comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration.... The issue at this point in the process is which of the competing causes are generally capable of causing the patient's symptoms.' Second, the expert must eliminate all causes but one." Id. (quoting McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1253 (11th Cir. 2005)).
- "With regard to the first step, the district court must ensure that, for each possible cause the expert 'rules in' at the first stage of the analysis, the expert's opinion on general causation is 'derived from scientifically valid methodology." Id.
- "Thus, the experts' purported use of the differential etiology method 'will not overcome a fundamental failure to lay the scientific groundwork' for the theory.... "Id. (quoting McClain, 401 F.3d at 1252).
- "[W]e note that we have previously identified some of the scientifically valid methods for establishing general causation. For instance, we will admit expert opinions pursuant to *Daubert* that are supported by epidemiological studies, provided the expert explains how the findings of those studies may be reliably connected to the facts of the particular case. An expert's opinion will likely also survive *Daubert* if the expert describes the physiological process, derived by the scientific method, by which a particular cause leads to the development of a given disease or syndrome." Id. at 1196-97 (internal citation and footnote omitted).

• "In the second step of the differential etiology analysis, the expert must eliminate all causes but one. While the first step focuses on general causation, in the second step the expert applies the facts of the patient's case to the list created in the first step in order to form an opinion about the actual cause of the patient's symptoms, *i.e.*, to determine specific causation.... [A]n 'expert must provide reasons for rejecting alternative hypotheses using scientific methods and procedures and the elimination of those hypotheses must be founded on more than subjective beliefs or unsupported speculation." *Id.* at 1197 (quoting *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1058 (9th Cir. 2003)).

Guinn v. AstraZeneca Pharms. LP 602 F.3d 1245 (11th Cir. 2010)

Factual Summary

A patient who used the antipsychotic drug Seroquel brought a products liability action against the drug manufacturer, alleging that it caused her to develop diabetes. The plaintiff offered testimony from Dr. Jennifer Marks on the issue of specific causation. Based on a review of the plaintiff's medical history, specifically, her fluctuations in weight, as well as a review of the medical literature, Marks opined that the drug caused the plaintiff's diabetes. She did not attempt to rule out other causes. After conducting a Daubert hearing, the district court granted the manufacturer's motion to exclude Marks' testimony, concluding that she could not articulate a proper scientific methodology and her opinion "amounts to nothing more than inadmissible ipse dixit." Guinn, 602 F.3d at 1252 (quoting Guinn v. AstraZeneca Pharms., LP, 598 F. Supp. 2d 1239, 1243 (M.D. Fla. 2009)). On appeal, the Eleventh Circuit affirmed.

Key Language

• "Differential diagnosis 'is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.' Although a reliable differential diagnosis need not rule out all possible alternative causes, it must at least consider other factors that could have been the sole cause of the plaintiff's injury." *Guinn*, 602 F.3d at 1253 (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999)) (internal citation and footnote omitted).

- "When properly conducted, differential diagnosis can be a reliable methodology under *Daubert*. However, 'an expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient." *Id.* (quoting *McClain v. Metabolife Int'l Inc.*, 401 F.3d 1233, 1237 (11th Cir. 2005)) (internal citations omitted).
- "Temporal proximity is generally not a reliable indicator of a causal relationship." *Id.* at 1254.

Wilson v. Taser Int'l, Inc. 303 F. App'x 708 (11th Cir. 2008)

Factual Summary

A state police officer and his wife brought a products liability action against the manufacturer of an electrical stun gun, alleging that it failed to warn of the risk of fractures, causing him to suffer a fractured spine during a training exercise. To support these claims, the plaintiffs offered testimony from Dr. Edward Meier, a treating physician, who opined that the officer's injuries were caused by exposure to the stun gun. This opinion was based on a review of the medical records, the opinions of his colleagues, his treatment of the officer, and his training and expertise. The district court granted the manufacturer's motion to exclude, concluding that Meier's opinion lacked reliability and used an improper methodology. The Eleventh Circuit affirmed.

- "Although a medical expert need not rule out every possible alternative in order to form an opinion on causation, expert opinion testimony is properly excluded as unreliable if the doctor 'engaged in very few standard diagnostic techniques by which doctors normally rule out alternative causes and the doctor offered no good explanation as to why his or her conclusion remained reliable' or if 'the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' action and [the doctor] offered no reasonable explanation as to why he or she still believed that the defendants' actions were a substantial factor in bringing about that illness." Wilson, 303 F. App'x at 714 (quoting Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1358 (N.D. Ga. 1999)) (alteration in original).
- "A medical degree does not authorize [a doctor] to testify when he does not base his methods on valid science." Id.

McClain v. Metabolife Int'l, Inc. 401 F.3d 1233 (11th Cir. 2005)

Factual Summary

The plaintiffs claimed that an herbal weight-loss supplement containing ephedrine and caffeine caused three people to suffer from ischemic stokes and one to have a heart attack. The district court stated that it lacked sufficient knowledge on the scientific subject matter and that, without competing testimony produced by the defendants, it could not exclude the plaintiff's expert testimony. The defendants appealed the district court's decision on the grounds that it abused its discretion when it admitted the plaintiff's expert testimony. The appellate court assessed the expert's opinions regarding general and individual causation, discussing the importance of the dose-response relationship in toxic tort cases, and held that the district court erred in admitting the plaintiff's expert testimony. Experts: Dr. O'Donnell, Pharm. D. (pharmacy, pharmacology, & nutrition), Dr. Hashim Hakim (neurology).

Key Language

- "In his article, Dr. Eaton describes some key principles of toxicology that a court should consider in 'any attempt to establish whether a chemical exposure was causally related to a specific adverse effect or disease in an individual." *McClain*, 401 F.3d at 1242 (citing David Eaton, *Scientific Judgment and Toxic Torts—A Primer in Toxicology for Judges and Lawyers*, 12 J.L. & Pol'y 5 (2003)).
- "Beyond explaining the importance of the doseresponse relationship, Dr. Eaton offers four scientific criteria for proving causation between a chemical exposure and a particular illness in an individual. First, 'the toxic substance in question must have been demonstrated to cause the type of illness or disease in question.' This focuses on the issue of general causation.... Second, 'the individual must have been exposed to a sufficient amount of the substance in question to elicit the health effect in question.' This requires not simply proof of exposure to the substance, but proof of enough exposure to cause the plaintiff's specific illness. This focuses on the issue of individual causation.... Third, 'the chronological relationship between exposure and effect must be biologically plausible.' On this point Eaton explains that, "if a disease or illness in an individual preceded the established period of exposure, then it cannot be concluded that the chemical caused the disease, although it may be possible to establish that the chemical aggravated a pre-existing condition or dis-

- ease.'... The issue of the chronological relationship leads to another important point—proving a temporal relationship between taking Metabolife and the onset of symptoms does not establish a causal relationship. In other words, simply because a person takes drugs and suffers an injury does not show causation.... Fourth, and finally, 'the likelihood that the chemical caused the disease or illness in an individual should be considered in the context of other known causes.' This refers to the background risk of a specific disease—the risk that everyone faces of suffering from the same malady that a plaintiff claims without having exposure to the same toxin." *Id.* at 1242–43 (quoting Eaton, *supra*, at 38–40) (internal citations omitted).
- "...O'Donnell's use of FDA data and recommendations raises a more subtle methodological issue in a toxic tort case. The issue involves identifying and contrasting the type of risk assessment that a government agency follows for establishing public health guidelines versus an expert analysis of toxicity and causation in a toxic tort case." *Id.* at 1249.
- "The Reference Manual on Scientific Evidence explains that '[p]roof of risk and proof of causation entail somewhat different questions because risk assessment frequently calls for a cost-benefit analysis. The agency assessing risk may decide to bar a substance or product if the potential benefits are outweighed by the possibility of risks that are largely unquantifiable because of presently unknown contingencies....' Obviously, in a toxic tort case the court must focus on assessing causation, not on a cost-benefit analysis for restricting the sale and use of a drug." *Id.* (quoting Margaret A. Berger, *The Supreme Court's Trilogy on the Admissibility of Expert Testimony*, in *Reference Manual on Scientific Evidence* 33 (Fed. Jud. Ctr. 2d ed. 2000)).
- "Hakim used the 'differential diagnosis' approach to rule out all causes for plaintiff's injuries, except Metabolife 356.... This approach, however, will mot usually overcome the fundamental failure of laying a scientific groundwork for the general toxicity of the drug and that it can cause the harm a plaintiff suffered." *Id.* at 1252.

Rink v. Cheminova, Inc. 400 F.3d 1286 (11th Cir. 2005)

Factual Summary

The plaintiffs brought a class action suit against Cheminova, Inc. asserting products liability and toxic trespass claims stemming from their exposure to Fyfanon—

a pesticide sprayed over the Tampa Bay area to combat the Mediterranean fruit fly. The plaintiffs claim that the defendant stored the pesticide improperly, causing its key ingredient, malathion, to decompose into isomalathion—a chemical toxic to humans. The plaintiffs sought to introduce expert testimony to prove this chemical decomposition. The defendants filed a motion to exclude. The Eleventh Circuit upheld the district court's ruling that the methodology of the plaintiff's expert was not scientifically reliable under *Daubert*. Expert: Jack Matson, Ph.D. (chemical engineering).

Key Language

- "[T]he district court excluded Matson because 'the methodology by which he arrived at his ultimate conclusion is fundamentally flawed because it is not based on... sufficiently reliable data or facts." *Rink*, 400 F.3d at 1290.
- "In making this conclusion, the district court criticized Matson's method of extrapolating temperature data from one site to another without making particularized findings which accounted for the differences in conditions and length of storage at each site. In addition, the district court faulted Matson for: (1) his lack of prior experience with malathion, (2) his failure to visit the Fyfanon storage sites, (3) his failure to consider the testimony of workers at the various storage facilities, and (4) his continued use of certain data in later reports that had been deemed unreliable. In discussing this fourth flaw in Matson's methodology, the district court noted that the unreliability of his earlier data undermined his later calculations which used different methods but arrived at similar results." Id.

United States v. Gipson 383 F.3d 689 (11th Cir. 2004)

Factual Summary

The defendant appealed his conviction of two counts of bank robbery arguing, in part, that the underlying methodology of DNA profiler kits should be inadmissible under *Daubert*. The court affirmed the conviction, stating that the kits and their underlying methodology were scientifically reliable. Expert: Dolores Schoenbauer (forensic science).

Key Language

• "In applying the reliability requirement of *Daubert*, this court has drawn a distinction between, on the one hand, challenges to a scientific methodology, and,

- on the other hand, challenges to the application of that scientific methodology." *Gipson*, 383 F.3d at 696.
- "As our court's *Beasley* opinion explains, the rule in this circuit is that, when the application of a scientific methodology is challenged as unreliable under *Daubert* and the methodology itself is otherwise sufficiently reliable, outright exclusion of the evidence in question is warranted only if the methodology 'was so altered [by a deficient application] as to skew the methodology itself." *Id.* at 697.

Rider v. Sandoz Pharms. Corp. 295 F.3d 1194 (11th Cir. 2002)

Factual Summary

The plaintiffs brought a products liability action against the manufacturer of Parlodel alleging that they suffered strokes after taking the bromocriptine drug. The district court granted the manufacturer's motion to exclude the plaintiffs' proposed experts, and the Eleventh Circuit affirmed. Experts: Drs. Kenneth Kulig (toxicology, emergency medicine); Maurice Dukes (toxicology); Dennis Petro (neurology); Subir Roy (reproductive endocrinology); Anthony Guarino (pharmacology, toxicology).

- The methodology used by the proposed experts can be grouped into six categories: (1) epidemiological studies that may point weakly to causation; (2) case reports detailing injuries reported after ingestion of Parlodel; (3) dechallenge/rechallenge tests implying a relationship between Parlodel and stroke; (4) evidence that a class of drugs including bromocriptine may causes ischemic stroke; (5) animal studies indicating that bromocriptine may cause damage to some animals; and (6) the FDA statement withdrawing approval of Parlodel for preventing lactation. *Rider*, 295 F.3d at 1198.
- "This Court has long held that epidemiology is not required to prove causation in a toxic tort case." *Id.* at 1199. (The court obviously relied on other factors in affirming the district court.)
- "[Case reports] reflect only reported data, not scientific methodology. Some case reports are a very basic form report of symptoms with little or no patient history, description of course of treatment, or reasoning to exclude other possible causes." *Id.* "[W]hile they may support other proof of causation, case reports alone ordinarily cannot prove causation." *Id.*
- "[B]ecause none of the [dechallenge/rechallenge] studies involved a patient with the particular injury suffered by the plaintiffs, they do not provide data

- useful in determining whether Parlodel caused the plaintiffs' injuries." Id.
- "To admit the plaintiffs' evidence, the Court would have to make several scientifically unsupported 'leaps of faith' in the causal chain." *Id.* at 1202.
- "Courts are cautioned not to admit speculation, conjecture, or inference that cannot be supported by sound scientific principles. 'The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." Id. (quoting Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996)).

McCorvey v. Baxter Healthcare Corp. 298 F.3d 1253 (11th Cir. 2002)

Factual Summary

The plaintiff filed a product liability suit against the manufacturer and distributor of a catheter, after it spontaneously erupted and fragmented inside his body during surgery. In an effort to defeat summary judgment, the plaintiff retained an engineering expert, and the manufacturer successfully challenged the expert under Rule 702 and *Daubert*. The Eleventh Circuit affirmed.

Key Language

- The district court found that the methodology of the proposed engineering expert was not scientifically reliable, and his causation opinion was based wholly on speculation, because he did not test alternative designs for the catheter, he did not talk to medical personnel, he was unable to cite scientific literature in support of his theories, and he did not consider or test possibilities for failure that could have come from sources outside of the product, e.g., the effect of improper storage conditions, contaminants or human error. McCorvey, 298 F.3d at 1256-57.
- "Rulings on admissibility under Daubert inherently require the trial court to conduct an exacting analysis of the proffered expert's methodology." Id. at 1257.

Practice Tip

The court's emphasis on its gatekeeper role raises the bar higher in the Eleventh Circuit.

Mich. Millers Mut. Ins. Corp. v. Benfield 140 F.3d 915 (11th Cir. 1998)

Factual Summary

The defendant homeowners had a homeowner insurance contract with the plaintiff insurer. There was a fire in the home, and the insurer's proposed expert opined that

it was intentionally set because there was no accidental source of ignition where the fire originated (on top of the dining room table). The district court struck the proposed expert's testimony. The Eleventh Circuit affirmed. Expert: William Buckley (fire sciences, origin of fire).

Key Language

- The proposed expert reached his opinion by eliminating all accidental causes, and determining that there were no other possible sources of the fire's ignition. Benfield, 140 F.3d at 921. Essentially, the proposed expert reached his opinion because he could not identify the source of the fire's ignition. Id.
- The proposed expert performed no tests and took no samples in determining the fire was incendiary. Id. The proposed expert was unable at trial to describe the chandelier that hung over the table, and he could not explain the methodology he used to eliminate the chandelier as a possible source of the fire's ignition. *Id*.
- The proposed expert also said that lamp oil was poured from a lamp oil bottle found in the area, and that the lamp oil was set on fire, but he said that he did not know whether the lamp oil bottle contained any lamp oil before the fire, and the court stated that there was no scientific basis for this opinion. *Id*.

City of Tuscaloosa v. Harcros Chems., Inc. 158 F.3d 548 (11th Cir. 1998)

Factual Summary

Cities and public utilities boards sued distributors of chlorine, alleging price-fixing, bid-rigging, allocating markets, and conspiracy for sealed bid auctions for municipal chlorine procurement. One expert for the plaintiffs was a statistician who provided data showing, and testimony regarding the statistical significance of, market shares in the Alabama chlorine market, the frequency with which companies retained chlorine contracts with particular municipalities from year to year, the frequency of tie bids in the market, prices bid by the defendants, winning bid prices, and costs borne by the defendants. The Eleventh Circuit reversed the district court's exclusion of most of the statistician's testimony, and in so doing, analyzed his methodology. Expert: James McClave (statistician, on bidding patterns).

Key Language

• "[He] utilized well-established and reliable methodologies in the preparation of most of his statistics and his testimony. He generated the statistics underlying his testimony through simple compilation of data from the plaintiff municipalities' records, from

- documents and books obtained from the defendants through discovery, and from public sources." *City of Tuscaloosa*, 158 F.3d at 565–66.
- The expert's compilations of the data into measurements of bid prices, costs, tie bid frequencies, incumbency rates, and other measurements, as well as his testimony on estimated damages, were found by the court to be products of simple arithmetic, algebra, and multiple regression analysis. *Id.* at 566.
- Not every scientific or technical methodology applied by expert witnesses is susceptible to testing and retesting. Id. at 566 n.25. "Economic or statistical analysis of markets alleged to be collusive, for instance, cannot readily be repeatedly tested, because each such case is widely different from other such cases and because such cases cannot be made the subject of repeated experiments. The proper inquiry regarding the reliability of the methodologies implemented by economic and statistical experts in this context is not whether other experts, faced with substantially similar facts, have repeatedly reached the same conclusions (because there will be few or no cases that have presented substantially similar facts). Instead, the proper inquiry is whether the techniques utilized by the experts are reliable in light of the factors (other than testability) identified in Daubert and in light of other factors bearing on the reliability of the methodologies." *Id.*

Clarke v. Schofield 632 F. Supp. 2d 1350 (M.D. Ga. 2009)

Factual Summary

The father of a prison inmate brought a civil rights action against various corrections officers, alleging that they beat the decedent and placed him in five-point restraints, resulting in his death. An autopsy report concluded that the decedent died from a deep vein thrombosis ("DVT"). The plaintiff's purported medical causation expert, Dr. William Thompson, an emergency room physician, opined that the alleged beating caused a DVT to develop either in the decedent's right calf, because of a preexisting surgery, or his left thigh. He reached these conclusions by conducting a literature review and examining the decedent's autopsy report and other medical records. The defendants filed a motion to exclude, on the grounds that Thompson lacked the qualifications to render his opinions and that these opinions resulted from a flawed methodology. The district court granted this motion. Although it concluded that Thompson lacked the requisite qualifications, it found that, regardless of this finding, his

opinions were unreliable and therefore inadmissible. Specifically, after examining the *Daubert* factors and factors outlined in the Advisory Committee Notes to Rule 702, the court concluded that Thompson failed to satisfy any of them. As a result, the court excluded his testimony in its entirety.

- "This theory may qualify as some sort of medical casuistry but not as medical science. It does qualify, however, as a classic example of the *ipse dixit* of an expert.... Simply stated, just because someone has a medical degree or is board-certified in emergency medicine, that does not authorize him to testify about a theory not based on a solid foundation.... Here we have a genuine doctor presenting unsupported medical speculation. He cannot just make up facts to support his opinions—he cannot offer opinions that are 'educated guesses dressed up in evening clothes." *Clarke*, 632 F. Supp. 2d at 1363 (quoting *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1373 (N.D. Ga. 2001)).
- "It is patently obvious that Dr. Thompson cannot support this theory with sufficient evidence in the record. Indeed, the theory falls in the category of evidence that fails because it amounts to nothing more that what an attorney could argue in closing argument.... Too much speculation—not enough fact. This theory also smacks of the *post hoc ergo propter hoc* fallacy. This fallacy relies on a temporal relationship rather than a scientific relationship to an injury.... For many reasons, Dr. Thompson's left thigh theory does not work but chiefly because it relies on too much speculation and a lot of unproven data. Speculation and unproven data do not make for a reliable methodology." *Id.* (internal citations omitted).
- "His speculation and unfounded assumptions reduce the value of Dr. Thompson's opinions to 'the level of gossamer.' This Court, following the dictates of *Daubert*, will not let a jury get caught in this cobweb of speculation." *Id.* at 1365 (quoting *The Am. Bearing Co. v. Litton Indus., Inc.*, 729 F.2d 943 (3d Cir. 1984)).
- "This amounts to nothing less than wild speculation without any reliable support in the medical records. He has no training as an orthopedist. He makes an extensive diagnosis of a previous medical problem without any record to back it up, and even when he said that he wanted the records and did not get them, that did not stop him from offering the opinions. This is not a medical opinion; it is a medical fantasy fashioned out of wishful thinking." *Id.* at 1367.

Eberli v. Cirrus Design Corp. 615 F. Supp. 2d 1357 (S.D. Fla. 2009)

Factual Summary

The wife of an airplane pilot who crashed in the ocean brought negligence and strict liability claims against the aircraft manufacturer and the engine manufacturer, alleging that the plane's engine was defective, causing it to lock up and fail during flight. To support these claims, the plaintiff offered the testimony of several experts, including Donald Sommer, a purported piloting expert and accident reconstruction expert, including engine failure analysis. Sommer opined, in part, that the engine's "breather line" should have been in a different location, without conducting any testing or comparison with other engines. The aircraft manufacturer also offered testimony from experts, including David Klepacki, a purported failure analysis expert, who opined that the decedent's aircraft's engine failure was not caused by a defective "breather line." Klepacki's opinion was based on flight testing conducted by another expert. The district court granted the engine manufacturer's motion to exclude these opinions from both Sommer and Klepacki, concluding, inter alia, that their opinions rested on a flawed methodology.

Key Language

- "While it is true that 'an expert's testimony may be formulated by the use of the facts, data and conclusions of other experts,' such expert must make some findings and not merely regurgitate another expert's opinion." Eberli, 615 F. Supp. 2d at 1364 (quoting Ohio Envtl. Dev. Ltd. P'ship v. Envirotest Sys. Corp., 478 F. Supp. 2d 963, 976 (N.D. Ohio 2007)).
- "In this instance, it appears that Mr. Klepacki made no findings regarding the breather line; instead, it appears that he simply adopted [another expert's] conclusions regarding the flight tests. Such a methodology surely does not satisfy the Daubert standards." Id. at 1365.
- "Mr. Sommer's 'why not?' reasoning model cannot truly be considered a methodology at all, for it does not consist of steps or a process. In fact, his analysis does not even explore whether the engine's functioning would be affected by changing the location of the breather line or whether locating the breather line in the rear of the engine would sufficiently protect it from freezing temperatures; he just assumes. As such, the Court finds that Mr. Sommer's opinion that the breather line should have been located in the rear of the engine is not based upon a sufficiently reliable methodology and must be excluded." *Id.* at 1366–67.

- "While Plaintiff is correct that an expert need not rule out every possible explanation for an accident in drawing a conclusion, such expert cannot merely float unsubstantiated additional potential causes of the accident. Mr. Sommer's opinion regarding secondary possibilities is pure speculation and is, thus, inadmissible. In his testimony, Mr. Sommer even admits that the evidence he reviewed does not support any of his purported secondary possibilities for causation. In short, this opinion is exactly the type of speculation that the Rules of Evidence attempt to preclude." Id. at 1367 (internal citation omitted).
- "Mr. Sommer's conclusion that the accident was caused by the freezing of the breather line may very well have been the product of a reliable methodology, his opinion that an oil leak cannot be ruled out does not appear to have been reached by way of a reliable process or methodology. To the contrary, Mr. Coffman is merely proposing another hypothesis—one that he concedes is unlikely—because, as he seems to intimate, 'anything's possible.' As such, because it is the product of unreasoned speculation, Mr. Coffman's opinion regarding the possibility that an oil leak caused the accident must be excluded." Id. at 1368-69.

In re Accutane Prods. Liab. Litig. 511 F. Supp. 2d 1288 (M.D. Fla. 2007)

Factual Summary

In multi-district product liability proceedings, consumers alleged that an acne medication caused inflammatory bowel disease ("IBD") and psychiatric problems. To support their general causation claims, the plaintiffs offered testimony from Dr. Ronald Fogel, a gastroenterologist. Fogel reached his conclusion that the drug caused IBD after reviewing analogous animal and cell culture studies, studies on the biological plausibility of possible mechanisms of actions, internal documents from the manufacturer that contained studies, and case reports. The district court granted the defendant's motion to exclude Fogel's testimony, concluding that he employed an unscientific methodology and there was a gap between the data he relied upon and his opinions. As a result, it excluded his testimony.

Key Language

• "An expert's methodology must be consistent with the 'methods and procedures of science' rather than being founded on 'subjective belief or unsupported speculation.' When an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study. That is,

he must not draw overreaching conclusions." *In re Accutane Prods. Liab.*, 511 F. Supp. 2d at 1290–91 (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 592 (1993)).

- "An expert who ignores the dose-response relationship casts suspicion on the reliability of his methodology." *Id.* at 1293.
- "Dr. Fogel's willingness to reach conclusions based on documents that he does not understand indicates a bias of wanting to reach a particular conclusion. It casts suspicion on whether he blindly followed a scientific trail until reaching a conclusion, or whether the conclusion came first and then a trail was identified. At any rate, these documents do not support an opinion on causation.... Under *Daubert*, the reasoning or methodology underlying the testimony of an expert must be scientifically valid.... Any testimony elicited from Dr. Fogel or any of Plaintiffs' experts regarding the causality assessments will lack this scientific validity." *Id.* at 1297–98.

Benkwith v. Matrixx Initiatives, Inc. 467 F. Supp. 2d 1316 (M.D. Ala. 2006)

Factual Summary

A consumer brought an action against a nasal spray manufacturer, alleging that her use of the spray caused her to lose her senses of taste and smell. To support her claims, the plaintiff offered testimony from Dr. Bruce Jafek, who provided both general and specific causation opinions based on cadaver experiments, live studies conducted by others, epidemiological studies, and a review of the plaintiff's medical records. The district court concluded that Jafek's causation opinions were based on an insufficient methodology that caused him to improperly extrapolate from existing data. As a result, the court excluded these opinions.

Key Language

- "District courts should pay careful attention to an expert's consideration of the dose-response relationship when analyzing her methodology in toxic tort cases.... The reliability of an expert's methodology is suspect if she avoids or neglects the dose-response relationship." *Benkwith*, 467 F. Supp. 2d at 1328.
- "While Dr. Jafek has impressive credentials in the fields of otolaryngology and rhinology, his opinion in this case is not sufficiently relevant or reliable. He attempts to use animal studies without support for extrapolation to humans, cites 'epidemiologic studies' that fail to follow the fundamentals of epidemiology, makes unsupported analogies between different

chemical substances, performs unsound experiments, draws impermissible conclusions from other scientists' articles and experiments, and relies on irrelevant and unreliable data. In short, Dr. Jafek has not 'employ[ed] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 1332 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

Reid v. BMW of N. Am.

430 F. Supp. 2d 1365 (N.D. Ga. 2006)

Factual Summary

A service technician alleged that while looking under the hood of a customer's car to determine why the car was overheating, the radiator exploded without warning and caused second and third degree burns on his arms, body, and face. To support his strict liability, failure to warn, and negligence claims, the plaintiff sought to use the testimony of Dr. Kasbekar, a failure analysis and prevention expert. The defendants argued to exclude the testimony as speculative, questioning a methodology wherein Dr. Kasbekar failed to inspect the actual radiator involved. The court denied the defendant's motion. Expert: Dr. Arnad Kasbekar (failure analysis and prevention).

Key Language

- "Therefore, it is more common that engineering experts state that their opinions are not based upon any scientific method but on general experience and knowledge after a review of evidence." *Reid*, 430 F. Supp. 2d at 1370.
- "The Court concludes that Dr. Kasbekar's opinions as presented in his affidavit are sufficiently reliable under *Daubert*. Contrary to the BMW defendants' assertions, his opinions are not based on nothing more than speculation and conjecture but instead are based upon inter alia Dr. Kasbekar's review of photographs of the radiator, interview with plaintiff, review of thousands of documents, and his own experience analyzing similar failed radiators." *Id*.

United States v. Masferrer 367 F. Supp. 2d 1365 (S.D. Fla. 2005)

Factual Summary

The defendants were indicted on conspiracy to defraud and wire fraud charges. Allegedly, the defendants, former bank executives, devised a system of inter-bank loans designed to hide loan losses and artificially inflate the stock price of the bank's parent. The pros-

ecution sought to introduce expert testimony from a professor of international finance law regarding the true nature of the transactions and testimony from an investment banker and a certified public accountant regarding the valuation of the transactions. The court excluded the testimonies of all three, stating that the methodologies employed were unreliable and that the proposed testimony would not be helpful to the jury. Experts: Ross Buckley (international finance law), Timothy Seymour (investment banker/stock trader), Morris Hollander (certified public accountant).

Key Language

- "The methodology and the materials reviewed to conduct his analysis were; (1) approximately 170 trade letters, (2) trade slips, (3) faxes between the parties, (4) e-mails between the parties, (5) internal memoranda from one party to the other, (6) the SEC's depositions, and (7) trading conversations. Further, he read the complaint of the OCC, the Government's indictment against the Defendants, and reviewed his writings, books, and articles. He also stated that he did some research on the prices of the Latin American and Russian securities, and how well the Russian press was covering the media in the United States. He specifically looked at the coverage in the Wall Street Journal and the Miami Herald.... Mr. Buckley further testified that he did not, as part of his methodology, study any of the fundamentals of the city of Moscow loans, the collateral that might have been securing the loan, or the source of the re-payment of the loan." *Masferrer*, 367 F. Supp. 2d at 1374–5.
- "Mr. Buckley's methodology lacked the application of relevant material for the opinions he offered. For example, Mr. Buckley; (1) did not look at the fundamentals of the loans or the borrowers; (2) did not look at whether the loans were repaid; (3) did not look at whether or not the OCC required reserves on these loans; (4) did not look at whether any payments on these loans were affected by the moratorium; (5) did not do other research on value; and (6) did not review Hamilton Bank's portfolio...." Id. at 1375 (internal citations omitted).
- "Mr. Seymour testified that the methodology he used... to reach his conclusions were data bases like Bloomberg, Reuters, his propriety records from Troika, trading blotters, analysis that he has maintained, and industry reports from other big international banks such as IMG and Solomon Brothers that were prevailing reports in the market at that time... On Defendants' cross examination of Mr. Seymour,

he stated that he did not, and does not have any formal training in value analysis." Id. at 1376-7.

McGee v. Evenflo Co.

2003 U.S. Dist. LEXIS 25039 (M.D. Ga. Dec. 11, 2003)

Factual Summary

In a products liability lawsuit against defendant manufacturer of an allegedly defective child's car seat, parents of deceased child proffered an expert. The defendant filed a motion to exclude testimony. The district court granted the motion.

Key Language

- "[Expert] has not employed a clear methodology in reaching this conclusion. He merely assumes, and ultimately concludes, that as a general matter it is not desirable for a car seat to be designed to impact other portions of a car's interior..." McGee, 2003 U.S. Dist. LEXIS, at *27.
- "[T]he methodology employed by Brown in this case lacks sufficient indicia of reliability for his theories of product defect and alternative design to be admissible under the Federal Rules." *Id.* at *40.

Brasher v. Sandoz Pharms. Corp. 160 F. Supp. 2d 1291 (N.D. Ala. 2001)

Factual Summary

The plaintiffs brought an action against the manufacturer of Parlodel, alleging that they suffered strokes due to their post-partum ingestion of the drug. The Daubert issue was raised at summary judgment, and the court denied the defendants' motion. Experts: Drs. Patricia Coyle (toxicology); Kenneth Kulig (toxicology, emergency medicine); Denis Petro (neurology).

- The court stated that the experts' methodology, which included use of animal studies, case reports, and pharmacological comparisons of similar classes of drugs to infer conclusions as expressed in peer reviewed journals and textbooks, was sufficient. Brasher, 160 F. Supp. 2d at 1296.
- "Unquestionably, epidemiological studies provide the best proof of the general association of a particular substance with particular effects, but it is not the only scientific basis on which those effects can be predicted." Id.
- "In science, as in life, where there is smoke, fire can be inferred, subject to debate and further testing." Id.

Practice Tip

An example of a flexible, multi-factored approach.

Siharath v. Sandoz Pharms. Corp. 131 F. Supp. 2d 1347 (N.D. Ga. 2001)

Factual Summary

The plaintiffs brought a products liability action against the manufacturer of Parlodel, alleging that they suffered strokes after taking the drug bromocriptine. The defendant-manufacturer moved to exclude the plaintiffs' proposed experts, and the court granted the defendant's motion. Experts: Drs. Kenneth Kulig (toxicology, emergency medicine); Maurice Dukes (adverse drug reaction science); Dennis Petro (neurology); Subir Roy (reproductive endocrinology); Anthony Guarino (pharmacology, toxicology) on medical causation.

Key Language

- "[E]pidemiological studies provide the primarily generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or disease." *Siharath*, 131 F. Supp. 2d at 1356 (quotations omitted).
- In rejecting the plaintiffs' proposed expert, the court stated that "[t]his would be a different case if there was at least some support for the causal hypothesis in the peer-reviewed epidemiological literature, a predictable chemical mechanism, general acceptance in learned treatises and other scientific literature of a causal relationship, a plausible animal model, and dozens of well-documented case reports involving postpartum women with no other risk factors for stroke." *Id.* at 1370.
- The methodology of the everyday practice of clinical medicine "is not the sort of scientific methodology that *Daubert* demands." *Id.* at 1372.

Practice Tip

The methodology of everyday clinical medicine has a scientific basis, but it is more difficult to deconstruct than published studies and reports because it depends heavily on the training and experience of the individual clinician. To do so requires careful discovery from the clinical expert.

Webster v. Fulton County 85 F. Supp. 2d 1375 (N.D. Ga. 2000)

Factual Summary

In this case involving statistical questions regarding the county's use of racial, gender, or ethnic preferences in the awarding of contracts, among possibly other issues, the court denied the defendants' *Daubert* motion as untimely. The court also, however, denied the motion on its merits based on his utilization of well-established and reliable methodologies. Expert: Dr. George Easton (statistician, on disparate treatment).

Key Language

- The proposed expert generated his statistics by compiling data from county records and public sources, and he compiled that data into bid frequencies and availability of minority contractors, which was the product of simple arithmetic, algebra, and multiple regression analysis. *Webster*, 85 F. Supp. 2d at 1377–78.
- The proposed expert also employed the same methodologies as the defendants' expert statistician, and he utilized data sources that the defendants' expert stated were the best data sources available. *Id.* at 1378.

Senn v. Carolina E., Inc. 111 F. Supp. 2d 1218 (M.D. Ala. 2000)

Factual Summary

The plaintiff peanut farmers were successful at trial against a defendant agricultural chemical and services company that applied two fertilizers to the plaintiffs' crops because the defendant applied excessive rates of the chemicals, causing injury and stunted growth to the peanut seeds. Because at trial the court did not have the explicit guidance of *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), the court considered, on a renewed motion for judgment as a matter of law or motion for a new trial, whether the plaintiffs' expert's methodology was acceptable. The court denied the motion and accepted the expert's methodology. Expert: John Beasley, Ph.D. (weed scientist, on effects of herbicides).

Key Language

• At trial, the court found the expert's experience-based methodology reliable based on his response to questions about methodology and technique. *Senn*, 111 F. Supp. 2d at 1221. In forming his opinion, the expert stated that he relied on the following: (1) first-hand experience observing "field problems;" (2) that he has "assisted in work with previous weed science researchers looking at... potential problems related to excessive rates of herbicides;" (3) "many years in the field and seeing specific tests put out in the field, looking at what these herbicides, particularly the [chemical] can do, when excessive rates of the [chemical] are applied;" (4) "the fact that [he]

has helped put out field tests and helped examine the plants and [has] seen plants that were damaged by... excessive rates of particularly the [chemical]" and that, "when the soil has been analyzed...—it was ascertained that it was a high concentration of the chemical herbicide that caused that damage." Id. at 1221 n.5 (quoting from trial transcript).

- The court further found that the expert's methodology has been tested and subject to peer review, to the extent that weed scientists have authored publications and compiled data documenting damage to crops caused by an over application of the two fertilizers at issue. Id. at 1221.
- Even if all of the *Daubert* factors were not satisfied or applicable, the court found that the expert's methodology met the Daubert/Kumho standard of reliability. Id. "Specifically, the court finds that [the expert's] extensive background and experience in analyzing and ascertaining the causes of crop damage, coupled with his review of relevant publications and his work with other 'weed' scientists, provides an adequate basis upon which [the expert] can offer his opinion." Id.

Globetti v. Sandoz Pharms. Corp. 111 F. Supp. 2d 1174 (N.D. Ala. 2000)

Factual Summary

A patient brought an action against the pharmaceutical company that produced Parlodel because she suffered an acute myocardial infarction allegedly caused by the drug. At summary judgment, the defendant filed a Daubert motion against the plaintiff's experts, arguing that absent a scientifically appropriate epidemiological study, the experts' opinion is unscientific speculation. The court denied the motion, essentially adopting the plaintiffs' argument that the experts' methodology of looking at a variety of measures was appropriate. Experts: Drs. Finney, Cox, Waller, Kulig (cardiologists, on effects of drug).

Key Language

- Although epidemiological studies may constitute the best evidence, the experts relied on accepted and recognized scientific methodologies for assessing the possible side-effects and hazards associated with particular drugs and the causes of disease. Globetti, 111 F. Supp. 2d at 1179.
- The methodologies included animal studies, medical literature reviews, adverse drug reaction reports to the FDA, the "general acceptance" of the association reflected in several medical texts, the Larrazet experiment, and a doctor's observations in another case. Id.

 "One can debate the flaws and inadequacies of any element of the scientific evidence relied upon by the experts as a foundation for their testimony, but the validity of the methodologies cannot be seriously questioned." Id. at 1180.

Bailey v. Allgas, Inc. 148 F. Supp. 2d 1222 (N.D. Ala. 2000)

Factual Summary

A competitor brought an action against a liquid propane distributor for violation of the Robinson Patman Act, the Alabama Unfair Trade Practices Act, the Alabama Motor Fuel Marketing Act, and tortious interference. At summary judgment, the distributor brought a motion to strike the competitor's expert report on market analysis. The court granted the motion. Expert: William D. Gunther, Ph.D. (economist, on market definition).

- Although the court held that the Daubert factors did not apply in this case, it also stated in dicta that even under *Daubert* the proposed expert's opinions still would be excluded due to insufficient methodology. Bailey, 148 F. Supp. 2d at 1235–36.
- In this type of case, Eleventh Circuit law requires that the proposed expert's methodology must consider the location of competitors, the pricing practices of competitors, and the transportation costs of competitors. Id. at 1237.
- Furthermore, the relevant geographic market is not a certain radius around the plaintiff's service area, but rather the area of effective competition in which competitors generally are willing to compete for the potential consumer. Id. at 1236-37.
- The court's findings become clearer when it lists what was and was not considered in the proposed expert's methodology. Facts that were used: two phone calls to a receptionist of an out-of-state trade association to learn about the propane gas industry in general (as opposed to that industry in the alleged geographic market); surfing the Internet to review the home page of that trade association; reviewing a census report to determine the number of people living within a certain radius of the city in which the relevant company was located; reading a list of Fortune 500 companies and their return on assets; and reviewing some documents produced by the defendant. Id. at 1238. The proposed expert did not do the following: contact or read the depositions of plaintiffs or any of the competitors in the relevant area; review sales figures, cost data or prices of compet-

itors; review documents produced by any competitors; or make any independent determination of whether these competitors were competing with the plaintiffs or defendant. *Id*.

Edwards v. Safety-Kleen Corp. 61 F. Supp. 2d 1354 (S.D. Fla. 1999)

Factual Summary

The plaintiff in this wrongful death case alleged that the decedent's death was caused by his workplace exposure to benzene while using the defendant's machine parts cleaner. The court considered a number of experts under a *Daubert* motion, and excluded one, who opined on the amount of benzene exposure the decedent would have received while using the defendant's product, based on that expert's methodology. Expert: Dr. Melvyn Kopstein (on chemical exposure levels).

Key Language

- The court defined the proposed expert's methodology as the assumptions made and data relied upon in applying standard textbook formulae to the case facts, as well as the intermingling of well-established formulae in order to reach a particular conclusion. *Edwards*, 61 F. Supp. 2d at 1357.
- The proposed expert did not sufficiently address the issues of lateral diffusion, mass versus volume, and measurement of air flow—critical factors for providing an indicia of reliability with respect to the methodology. *Id.* at 1358.
- The court could not determine from the record whether the proposed expert's application of formulae is followed by other experts in the industry, and there was no reference to articles or papers validating his approach. *Id*.

Treadwell v. Dow-United Techs. 970 F. Supp. 974 (M.D. Ala. 1997)

Factual Summary

The plaintiff, a former employee of the defendant, alleged that she was allergic to epoxy resin in her workplace, causing her to develop multiple chemical sensitivity. She brought an action against her employer and certain individuals. At the summary judgment stage, the defendants challenged the expert testimony of the plaintiff's physician under *Daubert*. The court did not permit the expert to testify on multiple chemical sensitivity or the field of clinical ecology, but it did permit him to testify as the plaintiff's treating physician. It also permitted expert testimony on chemical sensi-

tivity to formaldehyde because the diagnosis was predicated on sound methodology. Expert: Dr. Andrew M. Brown (clinical ecologist, treating physician on multiple chemical sensitivity).

Key Language

- In reaching his conclusion on formaldehyde, the expert based his findings on a physical examination of the plaintiff, the positive results of a patch test administered by the plaintiff's previous doctor, the plaintiff's medical history as presented by her, and the results of the first skin tritation test. *Treadwell*, 970 F. Supp. at 982.
- The court stated that "[t]hese diagnostic methodologies are scientifically valid, having been subjected to positive peer review and publication, and are considered reliable by medical specialists in the area of otolaryngic allergy." *Id*.

Gess v. United States

991 F. Supp. 1332 (M.D. Ala. 1997)

Factual Summary

The plaintiffs are twelve people, including eleven infants, who brought an action under the Federal Tort Claims Act, alleging that injuries they suffered while under the care of the nursery ward of an Air Force hospital were caused by surreptitious injections of drugs by a hospital employee. In the first part of the bifurcated trial, the court found that the government had breached its duty of care and its duty to protect the injured from the criminal acts of third parties. The court also found that, as a foreseeable result of the breach, a disturbed medical aide harmed each of the plaintiffs. In the second phase of the trial, the court considered the specific injuries the plaintiffs had suffered, and which of the injuries were caused by the government's breach. The government argued that the plaintiffs' expert testimony on the effect of lidocaine on the human body must be excluded under Daubert. The court disagreed, even in the absence of clinical studies, stating that the inquiry into the methodology must be flexible. Expert: Dr. Richard Colan (toxicologist, on drug effects).

Key Language

• The expert's methodology included gathering all available medical information about the plaintiffs, researching the effects and chemistry of lidocaine on the body, reading every article on the long-term impact of lidocaine exposure, and considering potential alternative causes of plaintiffs' injuries. *Gess*, 991 F. Supp. at 1340. Using that methodology, the expert

- reached his conclusion based on his knowledge of the central nervous system and his extensive experience diagnosing and treating central nervous system disorders. Id. "Given all this, the Court cannot find that [the expert's] testimony on causation represents mere speculation or subjective personal belief." Id.
- Here, the expert cannot compare and contrast his theory to a body of clinical research or recruit a group of subjects to test his theory, due to the unique nature of the facts and the injury. Id. Furthermore, he has not had sufficient time to publish his theory or seek general acceptance of the scientific community, though he may do so at a later date. Id.
- The court stated that to hold the expert's testimony inadmissible due to a lack of conclusive clinical research would send the message that plaintiffs cannot recover until at least one deviant person has attempted to poison infants with lidocaine. Id. In other words, expert testimony cannot be excluded solely because no one ever has testified on the topic in other cases.

Haggerty v. Upjohn Co. 950 F. Supp. 1160 (S.D. Fla. 1996)

Factual Summary

The plaintiff brought a product liability action against the manufacturer of a prescription sleeping medication, alleging that inadequate warnings accompanied the drug. He suffered from a herniated disc and took the medication to aid in sleeping. He claims that he experienced amnesia and a bizarre change in his normal behavior that caused a number of injuries while taking the drug. The defendant contended that the plaintiff's conduct was due to misusing the drug by ingesting numerous tablets, taking the tablets with large quantities of alcohol, as well as to a psychiatric personality disorder. The defendant successfully moved in limine to exclude the plaintiff's lone proposed expert. Expert: Deborah Mash, Ph.D. (pharmacologist, on product defect).

Key Language

• The methodology of the proposed expert, who has a Ph.D. in pharmacology and is an Associate Professor of Neurology and Molecular and Cellular Pharmacology at the University of Miami Medical School, is based on the following: data of spontaneous reports of adverse medical events involving Halcion that were collected by the Food and Drug Administration (FDA); anecdotal case reports appearing in medical literature; references in a textbook to non-Halcion

- studies of psychomotor agitation in rats and mice; peer review articles summarizing primary clinical findings not read by the expert; newspaper articles and correspondence to the FDA from a public interest group, a secondary summary of a doctor that provided a detailed listing of primary citations with abstracts of primary findings; and European post-marketing surveillance reports. *Haggerty*, 950 F. Supp. at 1163.
- On whether the methodology has been subjected to the scientific method, the proposed expert admitted that she had not tested her causation opinion or subjected it to scientific scrutiny, and she had not conducted independent research on the alleged adverse side effects of Halcion. Id. at 1163-64. Furthermore, the spontaneous reports of adverse medical events contained raw information that had not been scientifically or otherwise verified as to cause and effect. Id. at 1164.
- The proposed expert's methodology also had not been subjected to scientific scrutiny through peer review. Id.
- The proposed expert's causation methodology had no known or acceptable rate of error because the hypothesis was not tested. Id. Indeed, the expert admitted that there was significant but unquantifiable error in the data because they were incomplete, and there were non-causation biases affecting the numbers in the reports. Id. In particular, some of the data contained methodological flaws and biases making it impossible to calculate an incidence rate. *Id*.
- There also was no general acceptance or support in the scientific community for the proposed expert's causation methodology. Id.
- The court also found that the methodology used by the proposed expert in her written findings was different than what she said in her testimony. Id. at 1165.

Practice Tip

A good example of how credentials cannot overcome flaws in methodology.

Byrnes v. Honda Motor Co.

887 F. Supp. 279 (S.D. Fla. 1994)

Factual Summary

The plaintiff was injured when the motorcycle he was riding was hit by an automobile. He brought an action against the motorcycle's manufacturer and other parties for failing to warn of the lack of crashworthiness and the absence of leg protection. At the summary judgment stage, the defendants successfully moved to preclude the opinions and testimony of the plaintiff's proposed expert under *Daubert* due to a general lack of methodology. Expert: Harry Peterson, Ph.D. (on product defect).

Key Language

- "[T]here appears to be no dispute that [the proposed expert] has proffered no particular leg-guarding device that would have lessened the damage to Plaintiff's lower extremities, nor has any such device been designed, built or tested." *Byrnes*, 887 F. Supp. at 282.
- "[I]t appears that [the proposed expert] has generated certain hypotheses regarding safety equipment for the motorcycle at issue, but has not tested his hypotheses in any recognizable, scientific manner." *Id.*
- "Furthermore, because [the proposed expert's] hypothetical design has not been constructed or tested, there exists no empirical data for peers to review or scrutinize." *Id*.
- "Additionally, because the hypothetical design is not used in the industry, it cannot be generally accepted. In fact, it appears that the motorcycle industry has thus far generally rejected the premise of any legprotecting device that would be feasible and effective." *Id.*

Chikovsky v. Ortho Pharm. Corp. 832 F. Supp. 341 (S.D. Fla. 1993)

Factual Summary

The mother of the plaintiff took Retin-A as an acne treatment while she was pregnant with the plaintiff. The plaintiff suffered birth defects, allegedly as a result of the mother taking Retin-A. At the summary judgment stage, the court considered the defendant's motion to exclude the plaintiff's proposed expert under *Daubert*. The plaintiff's proposed expert was excluded

by the court because his insufficient methodology on whether Retin-A is a teratogen did not lead to a scientifically valid conclusion. Expert: Dr. Bertman, M.D. (obstetrician/gynecologist, on causation).

Key Language

- The proposed expert did not rely on any published material in reaching his conclusion that topical application of Retin-A causes birth defects. *Chikovsky*, 832 F. Supp. at 345. In fact, the proposed expert was not aware of any published article or treatise reaching the conclusion that Retin-A causes birth defects. *Id*.
- There is no data supporting the proposed expert's theory that a pregnant woman's topical application of Retin-A during pregnancy causes birth defects, and there is a total lack of data on the issue. *Id*.
- Although the proposed expert testified that dosage matters in determining whether the drug acts as a teratogen, he had no studies on the drug and no data relating to the plaintiff on the issue. *Id.*
- His comparison of Retin-A with vitamin A and Accutane was lacking. *Id.* at 346.
- He also did not perform any genetic studies to determine whether there are genetic explanations for the plaintiff's birth defects, and indeed testified that he did not rule out that the birth defects were induced by a genetic cause. *Id*.

Practice Tip

Although in *Daubert*, like this case, the expert admissibility issue was presented as part of a motion for summary judgment, "*Daubert* motions," *i.e.*, motions in limine addressing *Daubert* issues, have become the most common vehicle.